

## Medical Policy



### Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea

#### ▼Description

A positive airway pressure (PAP) system is a non-invasive technique for providing low levels of air pressure from a generator to a nasal or oral mask interface. It is used in the treatment of obstructive sleep apnea when the indications and limitations of the policy are met. The only diagnosis code that supports coverage of a PAP device is Obstructive Sleep Apnea (Adult or Pediatric). Oral appliances for OSA (E0485 and E0486) must be processed and billed through a Dentist office.

#### ▼Policy

Continuous positive airway pressure devices are considered **reasonable and necessary** for Members meeting coverage criteria.

#### ▼Policy Guidelines

##### INITIAL COVERAGE:

A single level continuous positive airway pressure (CPAP) device (E0601) is covered for the treatment of obstructive sleep apnea (OSA) if criteria A – C are met:

- A. The member has a face-to-face clinical evaluation by the treating Physician prior to the sleep test to assess the member for obstructive sleep apnea.
- B. The patient has a Medicare or Health Plan-covered sleep test 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 member and/or their caregiver have received instruction from the supplier of the CPAP device and accessories in the proper use and care of the equipment.

If a claim for a CPAP (E0601) is submitted and all of the criteria above have not been met, it will be denied as not reasonable and necessary.

Apnea is defined as the cessation of airflow for at least 10 seconds.

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 of sleep without use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the AHI. Sleep time can only be measured in a Type I (facility based polysomnogram) or Type II sleep study (see descriptions below).

The respiratory disturbance index (RDI) is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the RDI. The RDI is reported in Type III, Type IV, and Other home sleep studies.

If the AHI or RDI is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (respectively) must be at least the number of events that would have been required in a 2 hour period (i.e., must reach greater than or equal to 30 events without symptoms or greater than or equal to 10 events with symptoms).

#### **PEDIATRIC PATIENTS (Ages 1 – 17):**

Symptoms of sleep apnea in children may present somewhat differently than in adults, depending upon age. Common symptoms during sleep includes: snoring, difficulty breathing, snorting or choking sounds, abnormal motor activity, heavy sweating, arousal from sleep, nightmares and bed-wetting at an inappropriate age. Daytime symptoms caused by the disruption of normal sleep and repeated nocturnal oxygen desaturation include daytime sleepiness, irritability, hyperactivity, disciplinary problems, learning problems and headaches. In addition, chronic breathing through the mouth may indicate nasal obstruction. Many times symptoms may be in relation to adenotonsillary hypertrophy and the symptoms are usually treated by removing the hypertrophic adenotonsillar tissue. In addition to obstructive sleep apnea, central apnea can also occur in children.

Polysomnogram results for children are considered abnormal when the apnea index (AI) is greater than one, an apnea/hypopnea index (AHI) is greater than five, blood carbon dioxide levels of 45mEq/L for more than 60 percent of sleep time or 50 mEq/L for more than 10 percent of sleep time and minimum O<sub>2</sub> saturation less than 92 percent.

Pediatric patients (ages 1 – 17) meeting criteria of sleep apnea: (must meet at least one):

- One obstructive apnea of any length per hour
- Any central apnea of any length associated with desaturation below 90 percent
- Peak end-tidal carbon dioxide values of >53 mmHg or end-tidal carbon dioxide values of >45 mmHg for more than 60 percent of total sleep time
- SaO<sub>2</sub> levels of <92 percent

Central sleep apnea:

- Polysomnogram with more than five central apneas per hour of sleep lasting 10 seconds or longer
- Polysomnogram with the presence of at least 10 central events per hour of sleep in the crescendo-decrescendo pattern

Exclusions: Diagnosis of snoring without sleep apnea

### **Oral appliances used for the treatment of Obstructive Sleep Apnea (reference only)**

Oral appliances used for the treatment of Obstructive Sleep Apnea (E0485 or E0486) require that the member has a covered sleep test that meets one of the following criteria ,however, **the oral appliance must be processed and billed through a Dentist's office.**

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, or
3. If the AHI>30 or the RDI> 30 and meets either of the following;
  - a. The member is not able to tolerate a positive airway pressure (PAP) device or
  - b. The treating physician determines that the use of a PAP device is contraindicated.

### **Respiratory Assist Devices E0470**

A RAD without backup rate (E0470) is covered for those patients with OSA who meet criteria A-C above, in addition to criterion D:

- D. A single level (E0601) positive airway pressure 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 member with OSA and criterion A- D are not met, it will be denied as not reasonable and necessary.

A bi-level positive airway pressure device with backup rate (E0471) is not medically 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 is subsequently substituted with an E0470 (RAD), 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.

Coverage, coding and documentation requirements for the use of RAD's for diagnoses other than OSA are addressed in the RAD policy.

Coverage of a PAP device for the treatment of OSA is limited to claims where the diagnosis of OSA is based upon a sleep test. (Type I, II, III, or IV). The sleep test must be either a polysomnogram performed in a facility-based laboratory (Type I study) or a home sleep test (HST) Types II, III, or IV, Other). The test must be ordered by the member's treating physician and conducted by an entity that qualifies as a Medicare or Health Plan provider of sleep tests and is in compliance with all applicable state regulatory requirements.

### **Sleep Tests:**

A **Type I sleep test** is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It is facility –based and must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), electro-oculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). 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.

A HST is performed unattended in the member's home using a portable monitoring device. A portable monitoring device for conducting an HST must meet one of the following criteria:

- A. **Type II device** - Monitors and records a minimum of seven (7) channels: EEG, EOG, EMG ECG/heart rate, airflow, respiratory movement/effort and oxygen saturation; or,
- B. **Type III device** - Monitors and records a minimum of four (4) channels: respiratory movement/effort, airflow, ECG/heart rate and oxygen saturation; or,
- C. **Type IV device** – Monitors and records a minimum of three (3) channels, one of which is airflow; or,
- D. **Other** - Devices that monitor and record a minimum of three (3) channels that include actigraphy, oximetry, and peripheral arterial tone and for which there is substantive clinical evidence in the published peer-reviewed literature that demonstrates that the results accurately and reliably correspond to an AHI or RDI as defined above. This determination will be made on a device by device basis.

For PAP devices with initial dates of service on or after Nov.1, 2008, all members who undergo a HST must, prior to having the test, receive instruction on how to properly apply a portable sleep monitoring device. This instruction must be provided by the entity conducting the HST and may not be performed by a DME supplier. Member instruction may be accomplished by either:

- 1. Face-to-face demonstration of the portable sleep monitoring device's application and use; or,
- 2. Video or telephonic instruction, with 24 hour availability of qualified personnel to answer questions or troubleshoot issues with the device.

For PAP devices with initial dates of service on or after Nov.1, 2008, all HST's (Type II, III, or IV, or Other) must be interpreted by a physician who holds either:

- 1. Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or
- 2. Current subspecialty in Sleep Medicine by a member board of the American Board of Medical Specialties; or
- 3. Completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or
- 4. Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) or the Joint Commission.

For PAP devices with coverage based on a facility-based polysomnogram (Type I) performed on or after January 1, 2010, the interpreting physician must meet one of the requirements listed above (1-4) for credentialing.

#### **ACCESSORIES:**

1. Accessories used with a PAP 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 reasonable and necessary.
2. 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 reasonable and necessary.

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

<b>Procedure Code</b>	<b>Usual Maximum Amount</b>
A4604	1 per 3 months
A7027	1 per 3 months
A7028	2 per 1 month
A7029	2 per 1 month
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 3 months
A7038	2 per 1 month
A7039	1 per 6 months
A7046	1 per 6 months

1. A PAP (E0601) device should include, as standard equipment, integrated heat and humidification.
2. For PAP (E0470, E0471, E0472) either a non-heated (E0561) or heated (E0562) humidifier is reasonable and necessary when ordered by the treating physician for use with a covered PAP (E0470, E0471, E0472).

#### **REPLACEMENT:**

If a PAP device is replaced during the 5 year reasonable useful lifetime because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation, sleep test, or trial period.

If a PAP device is replaced following the 5 year reasonable useful lifetime, there must be a face to face evaluation by their treating physician that documents that the member continues to use and benefit from the PAP device. There is no requirement for a new sleep test or trial period.

**EXCLUSIONS:**

A liner used in conjunction with a PAP mask is considered comfort/convenience item. There is no additional payment for liners used with a PAP mask. These products should be coded A9270 (Noncovered item or service).

**HCPCS Level II Codes and Description**

**Equipment:**

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).

E0472 RESPIRATORY ASSIST DEVICE , BI-LEVEL PRESSURE CAPABILITY, WITH BACKUP RATE FEATURE, USED WITH INVASIVE INTERFACE, E.G. TRACHEOSTOMY TUBE (INTERMITTENT ASSIST DEVICE WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE)

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, 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

#### ▼ Documentation Requirements

Items in this policy may be subject to the Affordable Care Act (ACA) 6407 requirements.

The Affordable Care Act (ACA) 6407 requires that the treating physician conduct a face-to-face examination during the six month period preceding the written order. The documentation must be received by the provider prior to delivery for certain DME items. The documentation must describe a medical condition for which the DME is being prescribed.

#### ▼ Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS



product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

#### ▼ Cross Reference to Related Policies and Procedures

Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents; November 2011.

National Government Services, Inc. Jurisdiction B DME MAC, Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea. Local Coverage Determination No. L33718; revised date October 1, 2015.

National Heritage Insurance Company (NHIC), Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea. Local Coverage Determination No. L33718. Durable Medical Equipment Medicare Administrative Carrier Jurisdiction A. Chico, CA: NHIC; revised October 1, 2015.

#### Applicable URAC Standard

Core 8	Staff operational tools and support
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#### Change/Authorization History

Revision Number	Date	Description of Change	Prepared / Reviewed by	Approved by	Review Date:
A	11-20-06	Initial Release	Rosanne Brugnoli	Ken Fasse	n/a
01	08-2007	Deleted HCPC codes K0553-K0555	Rosanne Brugnoli	Ken Fasse	n/a

02	03/2008	<p>Added: definition of Type IV device.</p> <p>Extended implementation dates for credentialing of physicians interpreting home sleep tests and facility-based polysomnograms.</p> <p>Requirement for beneficiary education by entity conducting home sleep test.</p> <p>Expanded dates during which members must be re-evaluated for documenting benefit from PAP therapy.</p> <p>Expanded dates for members switched from CPAP to RAD with less than 30 days remaining in initial trial period.</p> <p>Added: Requalifying after failed initial 12 week trial of PAP therapy.</p> <p>Documentation: Expanded dates for documentation of benefit from PAP therapy.</p> <p>Documentation of adherence to PAP therapy to allow visual inspection of usage data.</p> <p>Changed title from Continuous Positive Airway Pressure System (CPAP) to Positive Airway Pressure (PAP) Devices for the treatment of OSA to reflect addition of coverage for RAD's.</p> <p>Revised coverage criteria for CPAP to include home sleep testing and face-to-face clinical evaluation and re-evaluation.</p> <p>Use of RAD's for OSA from the Respiratory Assist Devices to this policy.</p> <p>Coverage criteria for changing from a CPAP to RAD's both before and after the first 3 months of PAP therapy.</p> <p>Added criteria for portable sleep monitoring devices.</p> <p>Added requirements for administering and interpreting home sleep studies</p> <p>Added Information about documenting adherence and clinical re-evaluation</p> <p>Epworth Sleepiness Scale can be found in the Master P&amp;P manual in the LCD.</p>	Susan Glomb	Ken Fasse	
03	12-.2008	Annual Review. No additional changes	Susan Glomb	Ken Fasse	
04	01-2009	Revised criteria for Type IV home sleep test device. Added resource to identify list of approved Type IV devices that do not report AHI/RDI based on direct measurement of airflow or thoracoabdominal movement. (WatchPAT-100)	Susan Glomb	Ken Fasse	
05	09-01-09	Added GA and GZ modifiers. Revised KX modifier Added information about the required use of KX, GA or GZ on claim lines for PAP devices and/or accessories.	Susan Glomb	Ken Fasse	
06	12-4-09	Annual Review. No changes.	Susan Glomb	Ken Fasse	Dec. 2009
07	12-03-10	Annual Review – No changes	Susan Glomb	Ken Fasse	Dec.2010
08	01-07-11	Delete least costly alternative language for Codes E0470 and E0471. Revised requirements for documenting ineffective therapy on E0601. Added: Program integrity manual instructions on refills of accessories. Revised types of sleep tests. Coverage of replacement devices and/or accessories.	Susan Glomb	Ken Fasse	Jan2011
09	04-19-11	Policy updated to reflect current changes.	Susan Glomb	Dr. B. Almasri	
09	07-05-11	Policy updated to reflect current changes.	Susan Glomb	Dr. B. Almasri	
10	07-20-11	Added Important Note to all Medical Policies	Susan Glomb	Dr. B. Almasri	

11	11-28-11	Annual Review. Added References to Policy	Susan Glomb	Dr. B. Almasri	Nov. 2011
12	04-04-12	Added reference to NH Medicaid	Susan Glomb	Dr. B. Almasri	
13	12-4-12	Annual Review – No changes	Susan Glomb	Dr. B. Almasri	Dec 12
14	12-18-13	Annual review with changes pending. Added further description to policy stating that the only diagnosis for coverage is OSA.	Susan Glomb	Dr. B. Almasri	Dec 2013
15	12-4-2014	Annual Review. Added: Items in this policy may be subject to the Affordable Care Act (ACA) 6407 requirements.	Susan Glomb	Dr. B. Almasri	
16	12-16-15	Annual Review. Added noncovered information regarding liners used with a PAP mask.	Lisa Wojno	Dr. B. Almasri	