

# MEDICAL POLICY



<b>SUBJECT: POSITIVE AIRWAY PRESSURE DEVICES: CPAP, BiPAP, APAP AND NONINVASIVE POSITIVE PRESSURE VENTILATORS</b>	<b>EFFECTIVE DATE: 07/02/99 REVISED DATE: 01/17/02, 02/20/03, 12/18/03, 01/20/05, 04/21/05, 03/16/06, 04/26/07, 06/26/08, 02/26/09, 04/28/11, 04/26/12 ARCHIVED DATE: 04/25/13 EDITED DATE: 04/24/14, 06/26/14, 08/28/14, 04/23/15, 04/28/16, 04/27/17, 08/25/17, 04/26/18, 06/28/18, 08/23/18 (DELETED: 07/16/09-04/28/11) PAGE: 1 OF: 10</b>
<b>POLICY NUMBER: 1.01.06 CATEGORY: Equipment/Supplies</b>	

- *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*
- *If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

## POLICY STATEMENT:

### I. Obstructive Sleep Apnea in adults:

Based upon our criteria and assessment of the peer-reviewed literature, *Continuous positive airway pressure (CPAP)* (HCPCS: E0601) has been medically proven to be effective and therefore **medically appropriate** for the treatment of obstructive sleep apnea *for an initial 90 day trial period* in adults who meet the following criteria:

- A. Polysomnography (PSG) or home sleep testing (HST) results documenting an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) of greater than 5 and less than 14 respiratory events per hour with a minimum of 10 respiratory events and associated symptoms of obstructive sleep apnea (OSA) (e.g., excessive daytime sleepiness, impaired cognition, and insomnia) or documented cardiovascular diseases, including hypertension, ischemic heart disease, or history of stroke; OR
- B. Polysomnography or HST results documenting an AHI or RDI of greater than 15 with a minimum of 30 respiratory events; and
- C. A compliance support plan between the treating physician and DME supplier has been established.
- D. Continuation of coverage after 90 day trial period when the following has been demonstrated:
  - 1. Improved AHI and symptom resolution during trial period; and
  - 2. Compliance has been demonstrated as defined by the use of the device for 70% of the night for an average of 4 or more hours per 24 hour period during a consecutive 30 day period.
- E. Patients who do not meet the initial 90 day trial for continuation of coverage are eligible to re-qualify for a CPAP device but must have a face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to CPAP therapy (e.g., documentation of failure of symptoms to resolve or improper fit of device and re-education of the patient regarding proper use of the equipment or re-fitting of masks)

### II. Obstructive Sleep Apnea in children:

Based upon our criteria and assessment of peer-reviewed literature, CPAP has been medically proven to be effective and therefore **medically appropriate** for the treatment of obstructive sleep apnea in children for the following indications:

- A. Failure of adenotonsillectomy to relieve OSA symptoms or a contraindication to surgical intervention or for whom there is a strong preference for a nonsurgical approach; AND
- B. Polysomnography results documenting an AHI or RDI of 5 or greater and associated symptoms of OSA. Common OSA symptoms in children include (but are not limited to) habitual snoring, disturbed sleep, and daytime neurobehavioral problems such as hyperactivity. Daytime sleepiness may be present, but is less common in children. Children with an AHI or RDI greater than 2 but less than 5 may be considered for CPAP if significant daytime symptoms exist; OR
- C. Polysomnography results demonstrating an AHI or RDI within normal ranges, but the child exhibits episodes of hypercarbia based on end-tidal CO<sub>2</sub> measurements greater than 53 mm Hg or the end-tidal CO<sub>2</sub> is greater than

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50 mmHg for 10 – 24% of the sleep time. The child must also exhibit associated symptoms of OSA. (M Stephan 2006, AC Halbower, et al. 2007).

- D. The diagnostic criteria for pediatric obstructive sleep apnea (OSA) as defined by the American Academy of Sleep Medicine (AASM) and International Classification of Sleep Disorders (ICSD) is below. *All* of the following criteria should be present for a child to be diagnosed with OSA:
1. Snoring, labored breathing, or obstructed breathing during the child's sleep.
  2. One or more of the following: paradoxical inward rib cage motion during inspiration, movement arousals, diaphoresis, neck hyperextension during sleep, excessive daytime sleepiness, hyperactivity, aggressive behavior, slow growth, morning headaches, or secondary enuresis.
  3. Polysomnography reveals one or more obstructive apneas or hypopneas per hour of sleep (e.g., an apnea hypopnea index greater than 1 event per hour).
  4. Polysomnography demonstrates either of the following:
    - a. frequent arousals from sleep associated with increased respiratory effort, oxyhemoglobin desaturation associated with apnea, hypercapnia during sleep, or markedly negative esophageal pressure swings; or
    - b. periods of hypercapnia, oxyhemoglobin desaturation, or both during sleep that are associated with snoring, paradoxical inward rib cage motion during inspiration, and either frequent arousals from sleep or markedly negative esophageal pressure swing.

### III. Snoring:

Based upon our criteria and the lack of peer-reviewed literature, *CPAP* is **not medically necessary** for the treatment of snoring without accompanying OSA.

### IV. Central Sleep or Complex Sleep Apnea:

- A. *Bilevel Positive Airway Pressure (BPAP)* (HCPCS: E0470) with or without rate control is considered a **medically appropriate** treatment option for *an initial 90 day trial period* in adults diagnosed with central sleep or complex sleep apnea who meet the following criteria :
1. central hypopnea/apnea greater than 50% of the total apnea hypopnea rate; or
  2. central hypopnea/apnea rate/index greater than 5 events per hour; and
  3. significant improvement of the sleep-associated hypoventilation while breathing the patient's prescribed FiO<sub>2</sub>.
- B. Continuation of coverage after 90 day trial period when the following has been demonstrated:
1. improved AHI and symptom resolution during trial period; and
  2. compliance has been demonstrated as defined by the use of the device for 70% of the nights for an average of 4 or more hours per 24 hour period during a consecutive 30 day period.

### V. Chronic respiratory failure:

Based upon our criteria and assessment of the peer-reviewed literature, *BPAP*, when used as noninvasive ventilatory support with or without the back-up rate feature, has been medically proven to be effective and therefore **medically appropriate** for *an initial 90 day trial period* in adults for the following indications:

- A. Restrictive thoracic disorders (e.g. neuromuscular disease, thoracic cage abnormalities) with documented:
1. oxygen desaturations less than or equal to 88% for at least 5 continuous minutes during sleep oximetry (minimum recording time of 2 hours) while the patient is either breathing room air or prescribed FIO<sub>2</sub> as applicable, or
  2. arterial blood gas PaCO<sub>2</sub> greater than or equal to 45 mm Hg while the patient is awake and breathing either room air or prescribed FIO<sub>2</sub> as applicable; or
  3. a documented decrease in forced vital capacity (FVC) or vital capacity (VC) to 50% of predicted; or
  4. a maximal inspiratory pressure of less than 60 cm H<sub>2</sub>O; or

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5. there is a symptomatic respiratory disease impairing activities of daily living;  
AND
  6. COPD does not contribute to the patient's pulmonary limitation.
- B. Severe chronic pulmonary disease with:
1. arterial blood gas PaCO<sub>2</sub> is greater than or equal to 52 mm Hg while the patient is awake and is breathing either breathing room air or prescribed FIO<sub>2</sub>, as applicable; AND
  2. oxygen saturations less than or equal to 88% for at least 5 continuous minutes during sleep oximetry (minimum recording time of 2 hours) while the patient is receiving oxygen at 2 LPM or prescribed FIO<sub>2</sub>, whichever is higher; AND
  3. OSA and treatment with CPAP has been considered and ruled out.
- C. Continuation of coverage after the 90 day trial period when the following has been demonstrated:
1. improved AHI and symptom resolution during trial period; and
  2. compliance has been demonstrated as defined by the use of the device for 70% of the nights for an average of 4 or more hours per 24 hour period during a consecutive 30 day period.
- VII. Replacement of a positive airway pressure device with an upgraded model will be reviewed for medical necessity and eligible for coverage if:
- A. the patient is compliant with use of the device (*please refer to continuation of coverage after 90 day trial*); and
  - B. the device is malfunctioning; and
  - C. the device has exceeded the warranty time period; and
  - D. required repairs would exceed the cost of a replacement device or the parts that need to be replaced; or
  - E. the patient has experienced a change in his or her physiological condition and meets criteria for continued use of the device; or
  - F. there has been irreparable change in the device's condition or in a part of the device, due to normal wear and tear.
- VIII. The monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified (HCPCS: A9279) is considered inclusive to the positive airway pressure device.
- IX. Devices used to clean or sanitize the CPAP or BPAP devices are considered a convenience item and are ineligible for coverage (e.g., SoClean<sup>®</sup>, SoClean 2 Go<sup>®</sup>, SoClean, Inc).
- X. The initiation and management of continuous positive airway pressure ventilation (CPAP) (CPT:94660) is considered **medically appropriate** when performed face-to-face AND criteria for a CPAP device have been met and the device has been approved.
- XI. Based upon our criteria and assessment of peer-reviewed literature, non-invasive positive pressure ventilators (NIPPV)(e.g., Trilogy100 (Phillips Respironics) (HCPCS: E0466) are considered **medically necessary** for home mechanical ventilation nocturnally (during sleep) for an initial 90 day trial period when
- A. CPAP or BPAP has failed; AND
  - B. In adults diagnosed with:
    1. Neuromuscular diseases; or
    2. Thoracic restrictive diseases; or
    3. Chronic respiratory failure consequent to chronic obstructive pulmonary disease with:
      - a. arterial blood gas PaCO<sub>2</sub> is greater than or equal to 52 mm Hg while the patient is awake and is breathing either breathing room air or prescribed FIO<sub>2</sub>, as applicable; AND

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- b. oxygen saturations less than or equal to 88% for at least 5 continuous minutes during sleep oximetry (minimum recording time of 2 hours) while the patient is receiving oxygen at 2 LPM or prescribed FIO<sub>2</sub>, whichever is higher; AND
  - c. OSA and treatment with BPAP has been considered and ruled out.
- C. Continuation of coverage after the 90 day trial period when compliance has been demonstrated as defined by the use of the device for 70% of the nights for an average of 4 or more hours per 24 hour period during a consecutive 30 day period.
- XII. Based upon our criteria and assessment of peer-reviewed literature, non-invasive positive pressure ventilators used to provide CPAP or bi-level CPAP (BPAP) therapy for the treatment of obstructive sleep apnea are considered not medically necessary.

*Refer to Corporate Medical Policy # 2.01.28 regarding Sleep Studies.*

*Refer to Corporate Medical Policy # 7.01.41 regarding Surgical Management of Sleep Disorders.*

**POLICY GUIDELINES:**

- I. BPAP, CPAP with expiratory relief (e.g., C- Flex technology (Respironics, Inc., Murrysville, PA), or APAP are options for patients who cannot tolerate the high constant air pressure associated with CPAP but wish to continue treatment for OSA.
- II. Supplemental oxygen and/or humidification can be added to positive pressure devices to increase oxygen saturation and decrease vasomotor rhinitis.
- III. Prior authorization is contract dependent. Please contact your local Customer (Provider/Member) Services Department to determine contract coverage. Eligibility for reimbursement is based upon the durable medical equipment benefits set forth in the member's subscriber contract.

**DESCRIPTION:**

Obstructive sleep apnea (OSA) in an adult is defined as the cessation of airflow through the nose and mouth for at least 10 seconds with a respiratory effort noted. Treatment for OSA is indicated when there is documented sleep related apnea by means of polysomnography or home sleep testing and evidence of clinical impairment such as increased sleepiness or altered cardiopulmonary function.

Obstructive sleep apnea in children is defined as a disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction that disrupts normal ventilation during sleep and normal sleep patterns. In pediatric OSA, the cessation of airflow through the nose and mouth lasts for at least 2 respiratory cycles rather than a time duration of 10 seconds as in an adult. Though adenotonsillectomy is the first-line therapy for pediatric OSA, surgery alone may not be sufficient or may be contraindicated. Continuous positive airway pressure may be an option for these patients. Obstructive hypoventilation (OH) in children is a sleep related breathing disorder that is considered a variation of obstructive sleep apnea. Children with OH may have an AHI within normal ranges, but have episodic periods of hypercarbia as evidenced by elevated measurements in the end-tidal CO<sub>2</sub>.

Central sleep apnea is defined as the cessation of airflow through the nose and mouth for at least 10 seconds with no respiratory effort noted. The cessation in breathing can be caused by problems involving brain mechanisms, or an obstructive component. Approximately only 4% of patients undergoing PSG in a sleep laboratory are diagnosed with central sleep apnea, making this an uncommon condition.

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Mixed sleep apnea is a combination of obstructive and central sleep apnea. Not only does the patient have an obstruction in the airway, but the patient may have a neurological dysfunction or cardiopulmonary as well that contributes to the central apnea component.

*Continuous positive airway pressure, or CPAP*, supplies constant pressure throughout the respiratory cycle by raising the intraluminal upper airway pressure above the positive critical transmural pressure of the pharynx or hypopharynx. The pressure is delivered by a flow generator through either nasal mask or modified nasal prongs in order to keep the upper airway patent resulting in adequate ventilation and arterial oxygenation. The pressure used is determined individually, with a range of 3 to 20 cm. water.

*Bilevel Positive Airway Pressure, or BPAP*, is an airway support system, which provides two different levels of pressure delivered via a mask. There is a higher pressure during inspiration and a lower pressure level during expiration. It is an option for patients who cannot tolerate the high constant air pressure associated with CPAP. Bilevel PAP devices with volume and/or pressure with a backup rate feature are types of ventilators that can be used for many applications (as described below) but have not shown effectiveness for treating OSA.

Bilevel positive pressure airflow is also used in noninvasive ventilation for patients with chronic respiratory failure. Outpatient noninvasive positive pressure ventilation has been used in the following situations:

- I. at night for the management of chronic respiratory failure,
- II. for the long term management of neuromuscular disorders with respiratory involvement,
- III. for patients with respiratory insufficiency due to severe kyphoscoliosis, or
- IV. for the improvement of nighttime desaturation and hypoventilation in patients with chest-wall diseases.

*Auto-or self-titrating positive airway pressure, or APAP*, systems utilize an algorithm that uses a pressure transducer and microprocessor to monitor the airway for vibration patterns and then makes air pressure adjustments based on the incidence of apnea or absence of vibration. APAP devices are also referred to as demand positive airway pressure devices (DPAP).

*CPAP with expiratory relief* (e.g., C-Flex technology (Respironics, Inc., Murrysville, PA) is designed to provide pressure relief during expiration, while maintaining optimal pneumatic splinting for effective therapy. *CPAP with expiratory relief* technology monitors the patient's airflow during expiration and reduces expiratory pressure proportional to expiratory flow. CPAP with C-Flex technology can increase compliance in those patients who find it difficult or uncomfortable to breathe out against the continuous positive pressure. This technology can be applied to CPAP, BPAP and APAP devices.

Most PAP machines now contain data cards which have the ability to record and transmit daily use rates of the device. In addition, most PAP machines can also be equipped with a modem (either wired or wireless) that is capable of transmitting data on a daily basis to a manufacturer-owned database. The ability to detect disturbances in a variety of measures, including air flow, amount of time used, and mask leak, is also included in most commercially available PAP machines.

### **RATIONALE:**

CPAP is effective in the treatment of adult patients with documented obstructive sleep apnea. The symptoms associated with obstructive sleep apnea (OSA) such as excessive daytime sleepiness, impaired cognition, and mood disorders are reduced or eliminated with the consistent use of CPAP. CPAP is not indicated in individuals with simple snoring that is not associated with pauses in respirations. Treatment recommendations for obstructive sleep apnea are based primarily on the respiratory disturbance index (RDI) or the apnea hypopnea index (AHI), the severity of the presenting symptoms and the existence and severity of co-morbid conditions. (The RDI is defined as the total number of obstructive apneas,

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hypopneas and respiratory event related arousals per hour; the AHI is defined as the total number of apneas and hypopneas per hour).

Current studies conclude that the extent of improvement in excessive daytime sleepiness is similar between CPAP and APAP. There is no clinical evidence that supports the use of APAP without the results of polysomnography or its use while waiting for polysomnography to be completed.

Comparative studies of CPAP and CPAP-C-Flex have demonstrated similar outcomes in the improvement of OSA. The addition of C-Flex can result in increased comfort and improved compliance in patients who are intolerant of the constant expiratory pressure of traditional CPAP.

Obstructive sleep apnea in children is a common condition that can result in severe complications if left untreated. Complications may include growth abnormalities, neurologic disorders, and cor pulmonale, especially in severe cases. Polysomnography is the best diagnostic technique shown to quantitate the sleep abnormalities associated with sleep disordered breathing, but there is an absence of widely accepted normative data for AHI/RDI in children. Adenotonsillectomy may be a surgical option for children with OSA. For those patients with specific surgical complications, minimal adeno-tonsillar tissue or persistent OSA after adenotonsillectomy, CPAP, observation, medications and additional upper airway surgeries are treatment options.

Positive Airway Pressure has not been approved by the FDA for use in children less than 7 years of age.

**CODES:**      Number                      Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

**CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

**CPT:**              94660                      Continuous positive airway pressure ventilation (CPAP), initiation and management  
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**HCPCS:**          A7027-A7039          Accessories/supplies, code range for positive pressure airway devices (code range)  
A7044- A7046          Accessories/supplies, code range for positive pressure airway devices (code range)  
A9279                    Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified  
E0466                    Home ventilator, any type, used with noninvasive interface, (e.g., mask, chest shell)  
E0470                    Respiratory assist device, bi-level pressure capability, without back-up 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 backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

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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)
E0561	Humidifier, nonheated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous airway pressure (CPAP) device
<b>ICD10:</b>	
G47.00	Insomnia, unspecified
G47.10	Hypersomnia, unspecified
G47.20	Circadian rhythm sleep disorder, unspecified type
G47.30	Sleep apnea, unspecified
G47.8	Other sleep disorders
G47.9	Sleep disorder, unspecified
J96.00-J96.02	Acute respiratory failure (code range)
J96.90-J96.92	Respiratory failure, unspecified (code range)

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<p><b>SUBJECT: POSITIVE AIRWAY PRESSURE DEVICES: CPAP, BiPAP, APAP, AND NONINVASIVE POSITIVE PRESSURE VENTILATORS</b></p> <p><b>POLICY NUMBER: 1.01.06</b> <b>CATEGORY: Equipment/Supplies</b></p>	<p><b>EFFECTIVE DATE: 07/02/99</b> <b>REVISED DATE: 01/17/02, 02/20/03, 12/18/03, 01/20/05, 04/21/05, 03/16/06, 04/26/07, 06/26/08, 02/26/09, 04/28/11, 04/26/12</b> <b>ARCHIVED DATE: 04/25/13</b> <b>EDITED DATE: 04/24/14, 06/26/14, 08/28/14, 04/23/15, 04/28/16, 04/27/17, 08/25/17, 04/26/18, 06/28/18, 08/23/18</b> <b>(DELETED DATE: 07/16/09-04/28/11)</b> <b>PAGE: 9 OF: 10</b></p>
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**KEY WORDS:**

C-Flex, Demand, DPAP, Obstructive sleep apnea, OSA, noninvasive positive pressure ventilatoin.

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## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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There is currently a Local Coverage Determination (LCD) for Positive Airway Pressure Devices for the Treatment of Obstructive Sleep Apnea. Please refer to the following LCD website for Medicare members:  
[https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33718&ContrId=389&ver=12&ContrVer=1&CtrctrSelected=389\\*1&Ctrctr=389&s=41&DocType=Active&bc=AggAAAQAAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33718&ContrId=389&ver=12&ContrVer=1&CtrctrSelected=389*1&Ctrctr=389&s=41&DocType=Active&bc=AggAAAQAAAAAA%3d%3d&)

There is currently a National Coverage Determination (NCD) for Durable Medical Equipment. Please refer to the following NCD website for Medicare members: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?&NCDId=190&ncdver=1&NCDSect=280.1&bc=BEAAAAAAQAAAA==&>