MEDICAL POLICY

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Medical Policy Details	
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Obstructive Sleep Apnea in Adults:
   A. 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, is considered **medically appropriate** for the treatment of obstructive sleep apnea *for an initial 90 day trial period* in adults who meet **ONE** of the following criteria:
      1. Polysomnography (PSG) or home sleep testing (HST) results documenting an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) of greater than five, and less than 15 respiratory events per hour and associated with 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**
      2. Polysomnography or HST results documenting an AHI or RDI of greater than, or equal to, 15 respiratory events per hour; **OR**
      3. Continuation after the 90-day trial; when the following have been demonstrated: *(Documentation required)*
         a. Improved AHI and symptom resolution during trial period; and
         b. Compliance has been demonstrated as defined by the use of the device for 70% of the nights for an average of four or more hours per 24-hour period during a consecutive 30-day period; **OR**
      4. Patients who do not meet the criteria for continuation of coverage during the initial 90 day trial for continuation of coverage are eligible to re-qualify for a CPAP device, but must have a 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).

B. Based upon our criteria and assessment of the peer-reviewed literature, *Bilevel positive airway pressure (BPAP or BiPAP)* (HCPCS: E0470 or E0471) with or without rate control is considered a **medically appropriate** treatment option for ***an initial 90-day trial period*** in adults diagnosed with obstructive sleep apnea who have failed CPAP or not tolerated CPAP when the following criteria has been met. *(Documentation required)*
   1. Demonstration of resolution/control of respiratory events with improved tolerance using BPAP at least two weeks after an acute episode **AND** the patient is stable on current treatment.
   2. Continuation of coverage after the 90-day trial period is considered **medically appropriate** when the following have been demonstrated. *(Documentation required)*
      a. Improved AHI and symptom resolution during trial period; **AND**
      b. Compliance has been demonstrated, as defined by the use of the device for 70% of the nights, for an average of four or more hours per 24-hour period, during a consecutive 30-day period.

II. Obstructive Sleep Apnea in Children:

Based upon our criteria and assessment of the peer-reviewed literature, CPAP has been medically proven to be effective and, therefore, is considered **medically appropriate** for the treatment of obstructive sleep apnea in children for the following indications: *(Please note that a 90-day continuation review is not required for pediatric members.)*

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 EITHER**:

B. Polysomnography results documenting an AHI or RDI of five 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 one but less than five 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_2 measurements greater than 53 mm Hg or the end-tidal CO_2 is greater than 50 mmHg for 10 to 24% of the sleep time. The child must also exhibit associated symptoms of OSA.

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, 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 one 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 considered **not medically necessary** for the treatment of snoring without accompanying OSA.

IV. Central Sleep or Complex Sleep Apnea/Treatment Emergent Sleep Apnea:

A. *Bilevel Positive Airway Pressure (BPAP)* (HCPCS: E0470 or E0471) 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 have failed CPAP or not tolerated CPAP and who meet the **ONE** of following criteria:
   1. central hypopnea/apnea greater than 50% of the total apnea hypopnea rate;
   2. central hypopnea/apnea rate/index greater than five events per hour;
   3. significant improvement of oxygenation while breathing the patient's prescribed FiO_2; **OR**
   4. documentation of demonstration of resolution/control of respiratory events with improved tolerance using BiPAP at least 2 weeks after an acute episode and patient is stable on current treatment.

B. Continuation of coverage after the 90-day trial period is considered **medically appropriate** when the following have been demonstrated. *(Documentation is required)*
   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 four 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, is considered **medically appropriate** for **an initial 90-day trial period** in adults who have failed CPAP and who meet 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 five continuous minutes during sleep oximetry (minimum recording time of two hours) while either breathing room air or prescribed FIO_2 as applicable, **OR**
   2. arterial blood gas $PaCO_2$ greater than or equal to 45 mm Hg while awake and breathing either room air or prescribed FIO2 as applicable; **OR**
   3. documented decrease in forced vital capacity (FVC) or vital capacity (VC) to 50% of predicted; **OR**
   4. maximal inspiratory pressure of less than 60 cm H_2O; **OR**
   5. 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 $PaCO_2$ greater than or equal to 52 mm Hg while the patient is awake and is breathing either room air or prescribed FIO_2, as applicable; **AND**
   2. oxygen saturations less than or equal to 88% for at least five continuous minutes during sleep oximetry (minimum recording time of two hours) while receiving oxygen at 2 LPM or prescribed FIO_2, whichever is higher; **AND**
   3. OSA and treatment with CPAP have been considered and ruled out.

C. Continuation of coverage after the 90-day trial period is considered **medically appropriate** when the following have been demonstrated. *(Documentation is required).*

D. Improved AHI and symptom resolution during trial period; **AND**

E. Compliance has been demonstrated, as defined by the use of the device for 70% of the nights, for an average of four or more hours per 24-hour period, during a consecutive 30-day period.

VI. 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. There has been irreparable change in the device's condition or in a part of the device, due to normal wear and tear.

VII. The monitoring feature/device, stand-alone or integrated, any type, including all accessories, components and electronics, not otherwise classified (HCPCS: A9279) is **considered inclusive** to the positive airway pressure device.

VIII. Devices used to clean or sanitize the CPAP or BPAP devices are considered a convenience item and are **ineligible for coverage** (e.g., SoClean, SoClean 2 Go).

IX. The initiation and management of continuous positive airway pressure ventilation (CPAP) (CPT: 94660) is considered **medically appropriate** when performed in-person **AND** clinical criteria for a CPAP device have been met, and the device has been approved by the Health Plan.

X. Based upon our criteria and assessment of peer-reviewed literature, intermittent non-invasive positive pressure ventilators (NIPPV)(e.g., Trilogy100 Phillips Respironics) (HCPCS: E0466) are considered **medically appropriate** for home mechanical ventilation nocturnally (during sleep) for an initial 90-day trial period when:
   A. CPAP and BPAP have 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 $PaCO_2$ greater than or equal to 52 mm Hg while awake and breathing either breathing room air or prescribed FIO_2, as applicable; **AND**
         b. oxygen saturations less than or equal to 88% for at least five continuous minutes during sleep oximetry (minimum recording time of two hours) while receiving oxygen at 2 LPM or prescribed FIO_2, whichever is higher; **AND**
         c. OSA and treatment with BPAP (without or with back up rate) have been trialed and failed (with documentation).
   C. Continuation of coverage after the 90-day trial period is considered **medically appropriate** when compliance has been demonstrated as defined by the use of the device for 70% of the nights for an average of four or more hours per 24-hour period during a consecutive 30-day period during the 90-day trial. *(Documentation is required)*
   D. Continuation after one year will be based on compliance that has been demonstrated, as defined by the use of the device for 70% of the nights, for an average of four or more hours per 24-hour period, during the most *current* consecutive 30-day period.

Refer to Corporate Medical Policy #2.01.28 Sleep Studies.

Refer to Corporate Medical Policy #7.01.41 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. BPAP devices may or may not include a backup rate. BPAP devices with a backup rate are timed devices that supply a breath at a specific rate per minute. These devices will deliver a breath when the minimum number of breaths per minute has not been met by the user.

III. Supplemental oxygen and/or humidification can be added to positive pressure devices to increase oxygen saturation and decrease vasomotor rhinitis.

IV. Prior authorization requirements are contract dependent. Please refer to your Customer (Member/Provider) Services Department for contract information. Eligibility for reimbursement is based upon the durable medical equipment benefits set forth in the member's subscriber contract/rider.

V. Coverage is allowed for a one-month rental when the CPAP or BPAP device is malfunctioning and out of warranty, (and not associated with a manufacturer recall) while the device is being repaired.

DESCRIPTION

Obstructive sleep apnea (OSA) in an adult is defined as recurrent episodes of complete or partial obstruction of the upper airway leading to reduced or absent breathing during sleep for greater than 10 seconds. These episodes are termed "apneas" with complete or near-complete cessation of breathing, or "hypopneas" when the reduction in breathing is partial. Treatment for OSA is indicated when there is documented sleep related apnea by means of polysomnography or home sleep testing, as well as evidence of clinical impairment such as increased sleepiness or altered cardiopulmonary function. Long-term cardiovascular sequelae of untreated OSA include poorly controlled hypertension, heart failure, and atrial fibrillation (even after catheter ablation) and other arrhythmias OSA also increases the risk for nonalcoholic fatty liver disease, likely due to intermittent nocturnal hypoxia and sleep disruption.

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 two 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 asleep 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_2.

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. Only approximately only 4% of patients undergoing PSG in a sleep laboratory are diagnosed with central sleep apnea, making this an uncommon condition.

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. BPAP is an option for patients who cannot tolerate the high constant air pressure associated with CPAP. BPAP devices with volume and/or pressure with a back-up 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 a data card that has 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.

Non-invasive positive pressure ventilation involves the delivery of oxygen into the lungs via positive pressure without the need for endotracheal intubation. It is used in both acute and chronic respiratory failure but requires careful monitoring and titration to avoid complications. NIPPV is a type of mechanical ventilation that can be used at home to assist with taking a full breath and maintaining adequate oxygen supply in the body, especially while sleeping.

Intermittent positive pressure reduces the work of breathing through three different methods. By applying positive end-expiratory pressure (PEEP) through expiratory positive airway pressure (EPAP), positive pressure ventilation allows the body to overcome the dynamic intrinsic positive end-expiratory pressure threshold required to initiate a breath, as well as increasing lung compliance.

RATIONALE

CPAP is effective in the treatment of adult patients with documented obstructive sleep apnea (OSA). The symptoms associated with 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, 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 the use of APAP 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 U.S. Food and Drug Administration for use in children less than age seven years.

CODES

- *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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management

HCPCS Codes

Code	Description
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)
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

ICD10 Codes

Code	Description
E66.2	Morbid (severe) obesity with alveolar hypoventilation
G35	Multiple sclerosis
G47.00	Insomnia, unspecified

Code	Description
G47.10	Hypersomnia, unspecified
G47.20	Circadian rhythm sleep disorder, unspecified type
G47.30	Sleep apnea, unspecified
G47.33	Obstructive sleep apnea (adult) (pediatric)
G47.35	Congenital central alveolar hypoventilation syndrome
G47.8	Other sleep disorders
G47.9	Sleep disorder, unspecified
I50.9	Heart failure, unspecified
J39.8	Other specified diseases of upper respiratory tract
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9	Chronic obstructive pulmonary disease, unspecified
J95.2	Acute pulmonary insufficiency following nonthoracic surgery
J96.00-J96.02	Acute respiratory failure (code range)
J96.10-J96.12	Chronic respiratory failure (code range)
J96.20-J96.22	Acute and chronic respiratory failure (code range)
J96.90-J96.92	Respiratory failure, unspecified, unspecified whether with hypoxia or hypercapnia (code range)
J98.4	Other disorders of lung
J98.8	Other specified respiratory disorders

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*Key Article

KEY WORDS

BPAP, BiPap, C-Flex, Demand, DPAP, Obstructive sleep apnea, OSA, noninvasive positive pressure ventilation.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) L33718 for-Positive Airway Pressure (PAP) 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/view/lcd.aspx?lcdid=33718&ver=48&keyword=&keywordType=starts&areaId=all&docType=6%2C3%2C5%2C1%2CF%2CP&contractOption=all&hcpcsOption=code&hcpcsStartCode=E0601&hcpcsEndCode=E0601&sortBy=title&bc=1 accessed 12/01/23.

There is currently a Local Coverage Determination (LCD) L33800 for Respiratory Assist Devices. Please refer to the following LCD website for Medicare members:

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33800&ver=26&bc=AAAAAAAAgAAA&= accessed 12/01/23.

There is currently a National Coverage Determination (NCD) 280.1 for Durable Medical Equipment. Please refer to the following NCD website for Medicare members: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?&NCDId=190&ncdver=1&NCDSect=280.1&bc=BEAAAAAAAQAAAA==& accessed 12/01/23.