# MEDICAL POLICY



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Medical Policy Title	Positive Airway Pressure Devices: CPAP, BPAP, APAP and Noninvasive Positive Pressure Ventilators (NIPPV)	
Policy Number	1.01.06	
Current Effective Date	July 17, 2025	
Next Review Date	July 2026	

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to <u>Product Disclaimer</u>)

## **POLICY STATEMENT(S)**

Continuous Positive Airway Pressure and Auto-Adjusting Devices

- Continuous positive airway pressure (CPAP) and auto-adjusting positive airway pressure (APAP) devices (HCPCS: E0601) are **medically appropriate** for adults and children with obstructive sleep apnea (OSA) when the following criteria are met:
  - A. Initial 90-day trial (Adult) must meet **ONE** of the following indications:
    - 1. Polysomnography (PSG) or home sleep testing (HST) results documenting an apneahypopnea index (AHI) or respiratory disturbance index (RDI) of >5 (five), and <15 respiratory events per hour and **ONE** of the following associated symptoms:
      - a. Symptoms of OSA (e.g., excessive daytime sleepiness, impaired cognition, insomnia); **or**
      - b. Documented cardiovascular diseases, including hypertension, ischemic heart disease, or history of stroke;

#### OR

- 2. Polysomnography or home sleep test (HST) results documenting an AHI or RDI of ≥15 respiratory events per hour.
- B. For the initial 90-day trial (Children <18 years) must meet **ONE** of the following indications: (Please note that a 90-day continuation review is not required for pediatric members who are children.)
  - 1. Failure of adenotonsillectomy to relieve OSA symptoms;
  - 2. A contraindication to surgical intervention; or
  - 3. For whom a nonsurgical approach is strongly preferred;

### AND EITHER 4 or 5

4. Polysomnography results documenting an AHI or RDI of ≥5 and exhibits OSA symptoms; **or** 

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- 5. Polysomnography results demonstrating an AHI or RDI within normal ranges and the child exhibits OSA symptoms (e.g., excessive daytime sleepiness, impaired cognition, insomnia) and **ONE** of the following:
  - a. The child exhibits episodes of hypercarbia based on end-tidal CO<sub>2</sub> measurements >53 mm Hg; **or**
  - b. The end-tidal  $CO_2$  is >50 mmHg for 10 to 24% of the sleep time.
- II. CPAP (CPT: 94660) for the initiation and management of OSA is **medically appropriate** when the following indications have been met:
  - A. Performed in-person;
  - B. Clinical criteria for a CPAP device have been met; and
  - C. The device has been approved by the Health Plan.
- III. Continuation of coverage after the 90-day trial is **medically appropriate** when **BOTH** of the following have been demonstrated. (Documentation is required).
  - A. Improved AHI and symptom resolution during trial; and
  - B. Compliance has been demonstrated (e.g., defined by using the device for 70% of the nights, for an average of four (4) or more hours per 24-hour period, during a consecutive 30-day period).
- IV. Replacement of a positive airway pressure device (HCPCS E0601) will be reviewed for **medical necessity and eligible for coverage** when **ALL** of the following are met:
  - A. The patient is compliant with use of the device (Please refer to continuation of coverage after 90-day trial);
  - B. The device is malfunctioning;
  - C. The device has exceeded the warranty time;

# AND EITHER D or E

- 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.
- V. CPAP is **not medically necessary** for the treatment of snoring without accompanying OSA.

## Bilevel Positive Airway Pressure

VI. Bilevel Positive Airway Pressure (BPAP or BiPAP) (HCPCS: E0470 or E0471) with or without rate control for adults diagnosed with OSA, central sleep apnea, complex apnea, or chronic respiratory failure who have failed CPAP or cannot tolerate CPAP is **medically necessary** when the following criteria are met. (Documentation required):

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- A. Initial 90-day trial for adults diagnosed with:
  - 1. OSA must meet **BOTH** of the following indications:
    - a. Demonstration of resolution or control of respiratory events with improved tolerance using BPAP at least two (2) weeks after an acute episode; **and**
    - b. The individual is stable on current treatment.
  - 2. Central sleep, complex sleep apnea and treatment of emergent sleep apnea must meet **ONE** of the following indications:
    - a. Central hypopnea/apnea >50% of the total apnea hypopnea index rate;
    - b. Central hypopnea/apnea rate/index >5 (five) events per hour;
    - c. Significant improvement of oxygenation while breathing the individual's prescribed FiO2; **or**
    - d. Documentation of demonstration of resolution or control of respiratory events with improved tolerance using BiPAP at least two (2) weeks after an acute episode and patient is stable on current treatment.
  - 3. BPAP for chronic respiratory failure when used as noninvasive ventilatory support with or without the back-up rate feature is **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) and **ONE** of the following symptoms:
      - Oxygen desaturations ≤ 88% for at least five (5) continuous minutes during sleep oximetry (minimum recording time of two (2) hours) while either breathing room air or prescribed FIO2 as applicable;
      - ii. Arterial blood gas PaCO2 ≥45 mm Hg done while awake and breathing either room air or prescribed FIO2 as applicable;
      - iii. Documented decrease in forced vital capacity (FVC) or vital capacity (VC)  $\leq$  50% of predicted;
      - iv. Maximal inspiratory pressure of <60 cm H2O;
      - v. Oxygen desaturations ≤ 88% for at least five (5) continuous minutes during sleep oximetry (minimum recording time of two (2) hours) while either breathing room air or prescribed FIO2 as applicable;
      - vi. Arterial blood gas PaCO2  $\geq$ 45 mm Hg done while awake and breathing either room air or prescribed FIO2 as applicable;
      - vii. Documented decrease in forced vital capacity (FVC) or vital capacity (VC)  $\leq$ 50% of predicted;

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- viii. Maximal inspiratory pressure of < 60 cm H2O;
- ix. Symptomatic respiratory disease impairing activities of daily living; or
- x. Chronic pulmonary disease (COPD) does not contribute to the individual's pulmonary limitation.
- b. Individuals with severe COPD must meet **ALL** of the following indications:
  - i. Arterial blood gas PaCO2 ≥52 mm Hg while the patient is awake and is breathing either room air or prescribed FIO2, as applicable;
  - ii. Oxygen saturations ≤ 88% for at least five (5) continuous minutes during sleep oximetry (minimum recording time of two (2) hours) while receiving oxygen at 2 LPM or prescribed FIO2, whichever is higher; and
  - iii. OSA and treatment with CPAP have been considered and ruled out.
- VII. BPAP continuation (e.g., after the initial 90-day trial) is **medically appropriate** when **BOTH** of the following have been demonstrated:
  - A. Improved AHI and symptom resolution during trial period; and
  - B. Compliance has been demonstrated (e.g., using the device for 70% of the nights for an average of four (4) or more hours per 24-hour period during a consecutive 30-day period).

### Intermittent Non-Invasive Positive Pressure Ventilator (NIPPV)

- VIII. Intermittent non-invasive positive pressure ventilators (NIPPV)(e.g., Trilogy Evo) (HCPCS: E0466) is medically appropriate for home mechanical ventilation nocturnally (during sleep) for an initial 90-day trial period when:
  - A. CPAP and BPAP have failed; **AND** 
    - 1. Adults diagnosed with **ONE** of the following indications:
      - a. Neuromuscular diseases;
      - b. Thoracic restrictive diseases; or
    - 2. Chronic respiratory failure consequent to chronic obstructive pulmonary disease with **ALL** of the following:
      - a. arterial blood gas  $PaCO2 \ge 52$  mm Hg while awake and breathing either breathing room air or prescribed FIO2, as applicable;
      - b. oxygen saturations ≤ 88% for at least five (5) continuous minutes during sleep oximetry (minimum recording time of two (2) hours) while receiving oxygen at 2 LPM or prescribed FIO2, whichever is higher; and
      - c. OSA and treatment with BPAP (without or with back up rate) have been trialed and failed (with documentation).

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IX. Continuation of coverage of the NIPPV after the 90-day trial period is **medically appropriate** when compliance has been demonstrated (e.g., defined using 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)

# **RELATED POLICIES**

#### Corporate Medical Policy

2.01.28 Sleep Studies

7.01.41 Surgical Management of Sleep Disorders

### POLICY GUIDELINE(S)

- 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. 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.
- V. Individuals 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 individuals regarding proper use of the equipment or re-fitting of masks).
- VI. 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.
- VII. 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).

#### DESCRIPTION

#### Sleep Apnea

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Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing during sleep. These interruptions called apnea can occur hundreds of times per night which can lead to fragmented sleep and decreased oxygen levels resulting in daytime fatigue, cardiovascular problems, and other health issues.

## Obstructive Sleep Apnea (OSA)

Obstructive sleep apnea (OSA) is the most common form of apneas, caused by physical blockage of the upper airway typically due to relaxed throat muscles during sleep. 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. OSA in adults are commonly associated with obesity, male gender, aging, and anatomical factors. Symptoms may include loud snoring, witnessed apnea, gasping, excessive daytime sleepiness, and hypertension. 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 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.

OSA 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. In the pediatric population sleep apnea is often caused by enlarged tonsils and adenoids. Symptoms may include snoring, pauses in breathing, restless sleep, behavioral issues, and poor growth. OSA 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 disorder breathing. However, there is an absence of widely accepted normative data for AHI/RDI in children. Adenotonsillectomy is the first-line therapy for pediatric OSA. When surgery alone may not be sufficient or may be contraindicated, continuous positive airway pressure may be an option for these individuals. For those individuals with specific surgical complications (e.g., minimal adeno-tonsillar tissue or persistent OSA) after

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treatment options. 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 CO2. 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.

### Central Apneas

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 individuals undergoing PSG in a sleep laboratory are diagnosed with central sleep apnea, making this an uncommon condition.

#### Mixed Apneas

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 (CPAP)

CPAP is the gold standard treatment options for adults with documented 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 OSA are based primarily on the RDI or the AHI, the severity of the presenting symptoms, and the existence and severity of co-morbid conditions.

CPAP provides 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 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**

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 individuals 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

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noninvasive ventilation for individuals with chronic respiratory failure. Outpatient noninvasive positive pressure ventilation has been used in the following situations:

- At night for the management of chronic respiratory failure;
- For the long-term management of neuromuscular disorders with respiratory involvement;
- For patients with respiratory insufficiency due to severe kyphoscoliosis; or
- For the improvement of nighttime desaturation and hypoventilation in patients with chest-wall diseases.

## Auto- or Self-Titrating Positive Airway Pressure (APAP)

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 daily 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 (NIPPV)

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. NIV is increasingly being used to treat individuals with chronic respiratory failure (e.g., neuromuscular diseases, restrictive thoracic disorders, obstructive lung diseases), and other hypoventilation conditions. NIVPPV 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.

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#### SUPPORTIVE LITERATURE

The effects of CPAP on secondary cardiovascular disease prevention are highly debated. Sanchez-de la Torre et al (2023) conducted a systematic review and meta-analysis of individual participant data (IPD) from three randomized controlled trials (RCT, Sleep Apnea Cardiovascular Endpoints (SAVE), Impact of Sleep Apnea Syndrome in Acute Coronary Syndrome (ISAACC) and Randomized Intervention with CPAP in Coronary Artery Disease and Sleep Apnea (RICCADSAO)) to assess whether adherence to CPAP therapy reduces the risk of major adverse cardiac and cerebrovascular events (MACCEs) in individuals with OSA and established cardiovascular disease. The study included 4186 adults with cardiovascular disease and OSA. The primary outcome was the first MACCEs. Statistical analysis included one stage and two stage IPD meta-analysis as well as on treatment analysis using marginal structural models to assess the effects of CPAP adherence. A total of 691 MACCEs (16.5%) were observed, the CPAP group had 349 and the no CPAP group 342. The main outcome intention- to-treat analysis did not show a significant difference in MACCEs between the CPAP and the no CPAP group. The on- treatment analysis revealed good adherence to CPAP ( $\geq$ 4 hours per day) was associated with a reduced risk of MAACEs reoccurrence. Adherence to CPAP was associated with reduced MACCE recurrent risk suggesting that treatment adherence is a key factor in secondary cardiovascular prevention in individuals with OSA.

Patil et al (2019) conducted a systematic review and meta-analysis to evaluate the effectiveness of positive airway pressure therapy (PAP) for adults with OSA. PAP treatments were compared to no treatment and various PAP modalities (e.g., CPAP, APAP, and BIPAP). Outcomes evaluated included OSA severity(AHI or RDI), daytime sleepiness, blood pressure, motor vehicle crash risk, quality of life, cardiovascular events, all-cause mortality, and adherence to therapy. Literature search results in 336 studies of which 184 met inclusion criteria for meta-analysis. High quality evidenced showed that CPAP significantly reduces reduce AHI by 23 events/hour versus no treatment. The AHI was reduced by 86% from a mean of 32.7 event to 4.1 events/hour. Daytime sleepiness had a -2.4 points improvement (95% CI: -2.8 to 1.9) with CPAP in symptomatic individuals. Clinically significant improvement reported for sleep related guality of life (QOL), blood pressure reduction, and motor vehicle crash risk. Observational studies showed significant reduction in cardiovascular events and mortality. There was no significant difference in individual outcomes among CPAP, APAP and BIPAP. Evidence support using CPAP as a first line treatment option unless intolerance necessitates alternatives. In lab versus home base APAP initiation comparable outcomes. Educational behavioral interventions and telemonitoring significantly improved PAP adherence. Nasal masks improved adherence and reduced AHI more than oronasal masks. Humidification reduced side effects but did not improve adherence or clinical outcomes. A high confidence recommendation for CPAP reducing AHI and improving symptoms. Moderate confidence for QOL and blood pressure improvements. Uncertain benefits reported for asymptomatic or minimally symptomatic individuals. Overall CPAP therapy is effective in reducing OSA severity, improving sleepiness, and lowering blood pressure especially in symptomatic and hypertensive adults. Education and early behavioral support enhance adherence. Cardiovascular risk and mortality remain uncertain in randomized controlled trials (RCT), although observational data suggest possible long term health benefits.

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Wang et al (2019) conducted a systematic review to assess the effectiveness of home noninvasive positive pressure ventilation (NIPPV) (home mechanical ventilation (HMV), BPAP, or CPAP devices) in adults with chronic respiratory failure. 68 studies evaluating 53,733 patients were included. In patients with COPD, home BPAP (compared to no device) was associated with lower mortality, decreased need for intubations and hospital admissions, but no change in quality of life. In patients with COPD, HMV (compared individually with BPAP, CPAP, or no device) was associated with fewer hospital admissions. In patients with thoracic restrictive diseases, HMV (compared to no device) was associated with lower mortality. In patients with neuromuscular diseases, home BPAP (compared to no device) was associated with lower mortality and better quality of life. In patients with obesity hypoventilation syndrome, home HMV/BPAP (compared to no device) was associated with lower mortality. Current evidence was not available to assess the comparative effectiveness of many device capabilities on patient outcomes. Criteria to initiate home NIPPV and home respiratory services varied and were not validated in comparative studies.

# PROFESSIONAL GUIDELINE(S)

The National Institute for Health and Care Excellence (NICE, 2021)) Clinical Guidelines for Diagnosis and Management of Obstructive Sleep Apnea/Hypopnea Syndrome (OASAHS), Obesity Hypoventilation Syndrome (OHS) and Chronic Obstructive Pulmonary Disease with OSAHS (COPD-OSAHS overlap syndrome) in people over 16 years of age. Available from: <a href="https://www.nice.org.uk/guidance/NG202">https://www.nice.org.uk/guidance/NG202</a> [accessed 2025 Jun 12]

- Offering fixed-level CPAP in those with mild OSA when symptoms affect quality of life (QOL) and usual daytime activities if lifestyle changes alone have been unsuccessful or are considered inappropriate.
- APAP as an alternative to fixed-level CPAP in those unable to tolerate CPAP.
- In individuals who cannot tolerate or refuse CPAP, they recommend offering a customized mandibular advancement device.
- In individuals with moderate to severe OSA, CPAP is recommended as a treatment option, with APAP offered as an alternative in those unable to tolerate CPAP.
- A customized mandibular advancement device may be used if an individual refuses PAP or is unable to tolerate PAP.
- A positional modifier may be considered for those with mild to moderate positional OSA if other treatments are unsuitable or not tolerated, but this should not be a first-line treatment option.

The European Respiratory Society (ERS) and the American Thoracic Society (ATS, 2017)) Clinical Recommendation for NIV in Adults with Acute Respiratory Failure. Available from: <a href="https://www.thoracic.org/statements/guideline-implementation-tools/non-invasive-ventilation-for-acute-resp-failure.php">https://www.thoracic.org/statements/guideline-implementation-tools/non-invasive-ventilation-for-acute-resp-failure.php</a> [accessed 2025 Jun 12]

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- Bilevel NIV for individuals with ARF leading to acute or acute-on-chronic respiratory acidosis (pH <7.35) due to COPD exacerbation. (Strong recommendation, high certainty of evidence.)
- Either bilevel NIV or CPAP for individuals with ARF due to cardiogenic pulmonary oedema. (Strong recommendation, moderate certainty of evidence.
- Early NIV for immunocompromised individuals ARF. (Conditional recommendation, moderate certainty of evidence.)
- Due to the uncertainty of evidence ERS/ATS unable to offer a recommendation on the use of NIV for de novo ARF.
- NIV for individuals with post-operative ARF. (Conditional recommendation, moderate certainty of evidence.)
- NIV to dyspneic individuals for palliation in the setting of terminal cancer or other terminal conditions. (Conditional recommendation, moderate certainty of evidence.)
- NIV should not be used in the treatment of patients with established post-extubation respiratory failure. (Conditional recommendation, low certainty of evidence.

The American Academy of Pediatrics Clinical Guidelines for the Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome (2012). Available from: <a href="https://publications.aap.org/pediatrics/article/130/3/576/30284/Diagnosis-and-Management-of-Childhood-Obstructive?autologincheck=redirected">https://publications.aap.org/pediatrics/article/130/3/576/30284/Diagnosis-and-Management-of-Childhood-Obstructive?autologincheck=redirected</a> [accessed 2025 Jun 12]

- All children/adolescents should be screened for snoring.
- Polysomnography should be performed in children/adolescents with snoring and symptoms/signs of OSAS; if polysomnography is not available, then alternative diagnostic tests or referral to a specialist for more extensive evaluation may be considered.
- Adenotonsillectomy is recommended as the first-line treatment of patients with adenotonsillar hypertrophy.
- High-risk patients should be monitored as inpatients postoperatively.
- Patients should be reevaluated postoperatively to determine whether further treatment is required. Objective testing should be performed in patients who are high risk or have persistent symptoms/signs of OSAS after therapy.
- Continuous positive airway pressure is recommended as treatment if adenotonsillectomy is not performed or if OSAS persists postoperatively.
- Weight loss is recommended in addition to other therapy in patients who are overweight or obese.
- Intranasal corticosteroids are an option for children with mild OSAS in whom adenotonsillectomy is contraindicated or for mild postoperative OSAS.

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American Academy of Sleep Medicine (ASSM,2008)) Clinical Guidelines for the Manual Titration of Positive Airway Pressure in Patient with OSA. Available from: https://aasm.org/resources/clinicalguidelines/040210.pdf [accessed 2025 Jun 12]

- Pre-Titration Preparation: All candidates should receive PAP education, hands-on demonstration, careful mask fitting, and acclimatization. (Standard)
- Pressure Adjustment: Increase CPAP (or inspiratory and expiratory positive airway pressures (IPAP/EPAP for BPAP)) to eliminate respiratory events: apneas, hypopneas, respiratory effort-related arousals (RERAs), and snoring, or until maximum pressure is reached. (Consensus)
- Minimum Starting Pressures: Minimum starting CPAP should be 4 cm H<sub>2</sub>O for both pediatric and adult patients. For BPAP, the starting IPAP and EPAP should be 8 cm H<sub>2</sub>O and 4 cm H<sub>2</sub>O, respectively. (Consensus)
- Maximum Pressures: Maximum CPAP should be 15 cm H<sub>2</sub>O (or maximum IPAP 20 cm H<sub>2</sub>O on BPAP) for patients <12 years, and 20 cm H<sub>2</sub>O (or maximum IPAP 30 cm H<sub>2</sub>O on BPAP) for patients ≥12 years. (Consensus)
- BPAP Pressure Differentials: Minimum IPAP-EPAP differential is 4 cm H<sub>2</sub>O, and maximum is 10 cm H<sub>2</sub>O. (Consensus)
- Pressure Increase Intervals: Increase CPAP/BPAP by at least 1 cm H<sub>2</sub>O with an interval no shorter than 5 minutes, targeting the elimination of respiratory events. (Consensus)
- Apnea-Triggered Pressure Increase: Increase CPAP/BPAP if ≥1 obstructive apnea is observed in patients <12 years, or ≥2 apneas in patients ≥12 years. (Consensus)
- Hypopnea-Triggered Pressure Increase: Increase CPAP/BPAP if ≥1 hypopnea is observed in patients <12 years, or ≥3 hypopneas in patients ≥12 years. (Consensus)
- RERA-Triggered Pressure Increase: Increase CPAP/BPAP if ≥3 RERAs are observed in patients <12 years, or ≥5 RERAs in patients ≥12 years. (Consensus)
- Snoring-Triggered Pressure Increase: Increase CPAP/BPAP if ≥1 minute of loud snoring is observed in patients <12 years, or ≥3 minutes in patients ≥12 years. (Consensus)
- Split-Night Titration Algorithm: The titration algorithm for split-night studies should be identical to that of full-night studies. (Guideline)
- Transition to BPAP: If a patient is uncomfortable or intolerant of high CPAP pressures, or obstructive respiratory events continue at 15 cm H2O, switch the patient to BPAP. (Consensus)
- Selected Pressure Parameters: The selected CPAP or BPAP settings should reflect control of obstructive respiration, a low respiratory disturbance index (RDI), minimum SpO2 above 90%, and acceptable leak. (Consensus)
- Optimal Titration: An optimal titration reduces RDI <5 and should include supine REM sleep without continual interruptions. (Consensus)

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- Good Titration: A good titration reduces the overnight RDI to ≤10 or reduces baseline RDI by 50% (if baseline RDI <15) and should include supine REM sleep. (Consensus)
- Adequate Titration: An adequate titration reduces RDI to ≤10 and reduces the baseline RDI by 75% or meets criteria for optimal/good except that supine REM sleep did not occur. (Consensus)
- Unacceptable Titration: An unacceptable titration fails to meet any of the above grades. (Consensus)
- Repeat Titration Study: Consider repeating a titration if the initial titration was not optimal/good and, for split-night studies, fails to meet AASM criteria. (Consensus)

# **REGULATORY STATUS**

The United States Food and Drug Administration (FDA) regulates ventilator as medical devices. All noninvasive positive pressure devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: <u>https://www.fda.gov/medical-devices</u> [accessed 2025 Jun 9]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: <u>Medical Device Recalls | FDA</u> [accessed 2025 Jun 8]

Phillip Respironic in June 2021 recall certain ventilators, BPAP and CPAP machines because of potential health risks. The polyester based polyurethane foam used in these devices to reduce sound and vibration can breakdown and could be breathed in or swallowed by a person using the device. On April 9, 2024, the U.S. District Court for the Western District of Pennsylvania entered a consent decree of permanent injunction against Philips RS North America LLC ("Philips Respironics"), Respironics California LLC, and Philips Holding USA Inc. This decree restricts the production and sale of new CPAP, BiPAP and other devices at several Philips Respironics facilities in the United States until certain requirements are met. <u>https://www.fda.gov/news-events/press-announcements/federal-court-enters-consent-decree-against-philips-respironics-following-recall-certain-sleep</u> [accessed 2025 Jun 12]

# CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

### **CPT Codes**

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

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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

#### **HCPCS Codes**

## ICD10 Codes

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

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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
150.9	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

Medical Policy: Positive Airway Pressure Devices: CPAP, BPAP, APAP and Noninvasive Positive Pressure Ventilators (NIV) Policy Number: 1.01.06 Page: 16 of 18

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## SEARCH TERMS

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

### CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

LCD - Respiratory Assist Devices (L33800) [accessed 2025 Jun 12]

<u>LCD - Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718)</u> [accessed 2025 Jun 12]

NCD - Durable Medical Equipment Reference List (280.1) [accessed 2025 Jun 12]

# PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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.

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#### POLICY HISTORY/REVISION

#### **Committee Approval Dates**

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, 04/25/13 - 04/28/16, 04/27/17, 08/25/17, 04/26/18, 06/27/19, 06/25/20, 07/15/21, 03/24/22, 01/19/23, 01/18/24, 01/23/25, 07/17/25

Date	Summary of Changes
07/17/25	• Off cycle review. Added medically necessary criteria for initial request for cpap device when the individual has document AHI or RDI of greater than or equal to 15 respiratory events per hour.
01/01/25	Summary of changes tracking implemented.
07/02/99	Original effective date