Cohere Medicare Advantage Policy - Positive Pressure Ventilation

Clinical Guidelines for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

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Other Notices:

Policy Information:

Specialty Area: Sleep Medicine
Policy Name: Cohere Medicare Advantage Policy - Positive Pressure Ventilation
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Positive Pressure Ventilation

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1-5]

- Local Coverage Determination (LCD): Positive airway pressure (PAP) devices for the treatment of obstructive sleep apnea (L33718)
- Local Coverage Determination (LCD): Respiratory assist devices (L33800)
- Billing and Coding: Respiratory care (A57224)
- Billing and Coding: Respiratory care (A57225)
- Article: Positive airway pressure (PAP) devices for the treatment of obstructive sleep apnea (A52467)

Description

Positive pressure ventilation (PPV) can be delivered via noninvasive positive pressure ventilation (NIPPV) using a tight-fitting mask that covers the patient's nose or both the nose and mouth. NIPPV is administered via continuous positive airway pressure (CPAP), automatic positive airway pressure (APAP), or bilevel positive airway pressure (BiPAP). CPAP is used to treat obstructive sleep apnea (OSA); BiPAP is used for patients with OSA and obesity-hypoventilation syndrome (OHS).[6]

Medical Necessity Criteria

Indications

Positive pressure ventilation (PPV) is considered appropriate if **ANY** of the following is **TRUE**:

- For continuous positive airway pressure (CPAP) or automatic positive airway pressure (APAP) with **ANY** of the following:

- Obstructive sleep apnea (OSA)* in persons aged 18 years or older for an FDA-approved diagnostic sleep test (type I, II, III, IV, other)[1] with **ANY** of the following[7-9]:
  - Apnea hypopnea index (AHI) or respiratory event index (REI) is **ANY** of the following[10]:
    - 5–14.9 events per hour (mild OSA) with a condition and/or symptoms (e.g., cardiovascular, metabolic, renal, pulmonary, neuropsychiatric) with **ANY** of the following[1,11]:
      - Excessive daytime sleepiness; **OR**
      - Impaired cognition; **OR**
      - Mood disorders; **OR**
      - Insomnia; **OR**
      - Hypertension; **OR**
      - Ischemic heart disease; **OR**
      - History of stroke; **OR**
    - 15–29.9 events per hour (moderate OSA)[1,12]; **OR**
    - Greater than or equal to 30 events per hour (severe OSA)[12]; **OR**
  - Preoperative preparation that is intended to improve or optimize the patient's perioperative physical status[13]; **OR**
- OSA* in persons aged 1–17 years with **ALL** of the following:
  - AHI or REI is **ANY** of the following[14,15]:
    - 1-4 events per hour (mild OSA) with a condition and/or symptoms (e.g., cardiovascular, metabolic, renal, pulmonary, neuropsychiatric); **OR**
    - 5-9 events per hour (moderate OSA); **OR**
    - 10 or more events per hour (severe OSA); **AND**
  - **ANY** of the following:
    - Persistent OSA and the patient does not qualify for site-specific upper airway treatment[16]; **OR**
    - Persistent OSA with **ANY** of the following[17]:
      - Post-adenotonsillectomy; **OR**
      - Frequent snoring (3 times or more per week); **OR**
      - Labored breathing during sleep; **OR**
      - Gasps, snorting noises, or observed episodes of apnea; **OR**

        - Sleep enuresis (especially secondary enuresis) following at least 6 months of continence; **OR**
        - Sleeping in a seated position or with the neck hyperextended; **OR**
        - Cyanosis; **OR**
        - Headaches on awakening; **OR**
        - Daytime sleepiness; **OR**
        - Attention deficit hyperactivity disorder (ADHD); **OR**
        - Learning problems; **OR**
        - Underweight or overweight; **OR**
        - Tonsillar hypertrophy; **OR**
        - Adenoidal facies; **OR**
        - Micrognathia/retrognathia; **OR**
        - High-arched palate; **OR**
        - Failure to thrive; **OR**
        - Hypertension; **OR**
    - Upper airway resistance syndrome (UARS) with **ALL** of the following:
        - A CPAP device is to be used nightly[18]; **AND**
        - **ALL** of the following[19]:
            - AHI less than 5 events per hour; **AND**
            - A minimum SpO of greater than or equal to 92%, the presence of airflow limitation during sleep for greater than or equal to 5% of total sleep time; **AND**
            - Daytime sleepiness and/or fatigue; **OR**
- For bilevel positive airway pressure (BiPAP) with **ANY** of the following:
    - Failure of CPAP with **ANY** of the following:
        - The device is uncomfortable; **OR**
        - The patient is intolerant; **OR**
        - The patient has a contraindication; **OR**
        - CPAP was ineffective; **OR**
    - **ANY** of the following:
        - Central sleep apnea (CSA) with **ALL** of the following[20]:
            - Significant improvement of the sleep-associated hypoventilation is expected with the use of a respiratory assist device on the settings that will be

prescribed for initial use at home while breathing the beneficiary's prescribed FIO2[2]; **AND**
- **ANY** of the following:
  - CSA is related to congestive heart failure (CHF); **OR**
  - Initial treatment with CPAP therapy is to normalize the apnea-hypopnea index (AHI); **AND**
- An adaptive servo-ventilation (ASV) device is to be used nightly[21]; **OR**

- Chronic obstructive pulmonary disease (COPD) for **ALL** of the following[2]:
  - An arterial blood gas PaCO2, done while awake and breathing the patient's prescribed FIO2, is greater than or equal to 52 mm Hg; **AND**
  - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the patient's prescribed FIO2 (whichever is higher); **AND**
  - Before initiating therapy, sleep apnea and treatment with a CPAP device have been considered and ruled out*; **AND**
  - A BiPAP device is to be used nightly; **OR**
- Hypoventilation syndrome with **ALL** of the following[2]:
  - An initial arterial blood gas PaCO2 greater than or equal to 45 mm Hg (done while awake and the patient is breathing prescribed FIO2); **AND**
  - Spirometry shows an FEV1/FVC greater than or equal to 70%; **AND**
  - **ANY** of the following:
    - An arterial blood gas PaCO2 (done during sleep or immediately upon awakening, and the patient is breathing prescribed FIO2) that shows the patient's PaCO2 worsened by greater than or equal to 7 mm Hg compared to the initial arterial blood gas result above; **OR**

        - A facility-based PSG or HST demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events (i.e., AHI less than 5); **AND**
    - For obesity hypoventilation syndrome (OHS), the patient meets **ANY** of the following:
        - For the initial treatment of a stable ambulatory adult patient with OHS[22]; **OR**
        - Concurrent severe OSA (AHI greater than or equal to 30 events per hour) presenting with chronic stable respiratory failure; **AND**
    - A BiPAP device is to be used nightly; **OR**
- Restrictive thoracic disorders (e.g., progressive neuromuscular disease, thoracic cage abnormality) with **ALL** of the following[2,23]:
    - **ANY** of the following:
        - Chronic respiratory failure; **OR**
        - Sleep-related breathing disorders; **AND**
    - A BiPAP device is to be used nightly or more often as needed as the disease progresses; **AND**
    - **ANY** of the following[2]:
        - An arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2 is greater than or equal to 45 mm Hg; **OR**
        - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the beneficiary's prescribed recommended FIO2; **OR**
        - If the patient has neuromuscular disease, **ANY** of the following:
            - Maximal inspiratory pressure is less than 60 cm H20; **OR**
            - Forced vital capacity is less than 50% predicted; **OR**

        - COPD does not contribute significantly to the patient's pulmonary limitation[2]; **OR**
- Either a heated or non-heated humidifier is considered medically necessary for use with BiPAP or CPAP[1,2]; **OR**
- For continued coverage of BiPAP or CPAP beyond the initial 90-day period with **ALL** of the following:
    - Documentation stating that an in-person re-evaluation demonstrated improvement by the patient and continued use will likely provide additional improvement[1]; **AND**
    - The patient is compliant and uses the device for at least 4 or more hours a night for at least 70% of 30 consecutive nights[1,2,4]; **AND**
    - **ANY** of the following**:
        - The current device is in proper working order and the patient does not require another device; **OR**
        - Replacement of the current PAP device for **ANY** of the following[1,2]:
            - The PAP device has reached a 5-year reasonable useful lifetime (RUL)[2,5]; **OR**
            - Repairs, maintenance, or replacement are not covered under a manufacturer's warranty; **OR**
        - Replacement of either a heated or non-heated humidifier for use with BiPAP or CPAP with **ANY** of the following:
            - Continued resolution of symptoms and improved AHI on PAP therapy; **OR**
            - Device consistently used greater than or equal to 4 hours per night on 70% of nights; **OR**
            - The humidifier device is not operating; **OR**
            - DME supplier has physically evaluated the device and determined that it cannot be repaired; **OR**
            - The device to be replaced is no longer covered under a warranty.

*NOTE: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the patient does not suffer from some form of sleep apnea (OSA, CSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation.[2]

**NOTE: The patient's plan determines whether a device should be rented or purchased. General guidance is that when the rental cost exceeds the cost to purchase a device, consideration shall be given to purchase the device. The total covered cost cannot exceed the purchase or rental price.

Non-Indications

Positive pressure ventilation (PPV) is not considered appropriate if **ANY** of the following is **TRUE**:

- A bi-level positive airway pressure device with back up rate (CPT E0471) if the primary diagnosis is OSA[1]; **OR**
- The need for intubation[26]; **OR**
- Encephalopathy or altered mental status[26]; **OR**
- Hemodynamic instability[26]; **OR**
- Facial trauma or facial defects[26]; **OR**
- Airway obstruction secondary to a mass[26]; **OR**
- Anticipated need for prolonged mechanical ventilation[26]; **OR**
- Gastrointestinal bleeding.[26]

Definitions

Apnea Hypopnea Index (AHI): number of apneas and hypopneas per total sleep time.[10]

Respiratory Disturbance Index (RDI): number of apneas and hypopneas and respiratory effort-related arousals (RERAs) per total sleep time.[10]

Respiratory Event Index (REI): number of apneas and hypopneas per monitoring time.[10]

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management
E0470	Respiratory assist device, bi-level pressure

	capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0561	Humidifier, nonheated, used with positive airway pressure
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous positive airway pressure (CPAP) device

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of positive pressure ventilation (PPV). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Mask discomfort. While the incidence is high, mask adjustments or a new mask typically alleviate most discomfort. When there is a skin irritation or infection, topical steroids or antibiotics are prescribed.[27]
- Neuromuscular issues. Khan et al. (2023) discussed respiratory muscle weakness as a main complication for patients with neuromuscular diseases. Complications may include breathing disorders that are sleep-related, nighttime hypoventilation, improper ventilation, and decreased ability to mobilize secretions (which may lead to death).[23]
- Complications. In rare cases, hemodynamic compromise occurs. Corp et al. (2021) noted the impact of PPV on heart-lung interactions as well as "the longer-term impact of shear forces on lung tissue and inflammatory reactions secondary to mechanical ventilation and extrathoracic sequelae."[28]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Improved patient outcomes. Yeghiazarians et al. (2021) note that patients reported increased left ventricular function, less sympathetic tone, and myocardial oxygen consumption.[7]
- Avoidance of intubation. Positive pressure ventilation (PPV) with standard therapy for acute respiratory failure reduces the need for endotracheal intubation.[29]
- Reduced hospitalization and mortality.[7,30]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Evidence

Patil et al. (2024) discuss a systematic review by the Agency for Healthcare Research and Quality (AHRQ) of long-term outcomes and obstructive sleep apnea (OSA). Patients who received CPAP therapy showed stronger, statistically significant associations between CPAP treatment for OSA and reduced all-cause mortality, which remained when analyses included randomized control trials (RCTs) and non-RCTs. The studies also address excessive daytime sleepiness (EDS), which can increase symptoms of OSA. Therapy with CPAP has short-term benefits, and symptoms return when treatment is discontinued. The American Academy of Sleep Medicine (AASM) conducted a systematic review and meta-analysis of 33 RCTs. Overall, there is a high level of evidence for CPAP therapy for patients with EDS; the AASM also strongly recommends CPAP therapy.[31]

Masa et al. (2020) conducted an RCT on obesity hypoventilation syndrome (OHS) and cardiac dysfunction. The focus of the secondary analysis was the Pickwick Project, the largest multicenter RCT on OHS. A total of 196 patients with OHS and severe OSA were included; a 3-year timeframe was used to determine the efficacy of noninvasive ventilation (NIV) and CPAP. Of the patients, 102 received CPAP therapy, and 94 received NIV (two levels of pressure). Both therapies showed similar improvement, specifically left ventricular diastolic dysfunction and reduced left atrial diameter. Respiratory function and dyspnea also improved, thus demonstrating the efficacy of both CPAP and NIV. (ClinicalTrials.gov Identifier: NCT01405976).[32]

Wang et al. (2019) investigated the use of noninvasive positive pressure ventilation (NIPPV) for adults with chronic respiratory failure due to chronic obstructive pulmonary disease (COPD), thoracic restrictive disorders (TRD), neuromuscular disease (NMD), and obesity hypoventilation syndrome (OHS). The systematic review included 68 studies with a total of 53,733 patients. For all conditions, NIPPV demonstrated a significant reduction in mortality (statistically and clinically). Patients with COPD demonstrated decreased hospitalizations, intubations, and dyspnea. Patients with TRD, NMD, OHS, and other lung diseases demonstrated increased exercise tolerance, quality of life, and sleep quality; dyspnea and hospitalizations decreased.[33]

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