

Cohere Medical Policy Positive Pressure Ventilation

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Sleep Medicine

Policy Name: Cohere Medical Policy - Positive Pressure Ventilation

Type: $[\underline{\mathbf{X}}]$ Adult (18+ yo) | $[\underline{\mathbf{X}}]$ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Positive Pressure Ventilation

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).¹

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)* with ANY of the following²:
 - Persons aged 18 years or older with **ANY** of the following³⁻⁴:
 - Apnea hypopnea index (AHI) or respiratory event index (REI) is ANY of the following⁵:
 - 5–14.9 events per hour (mild OSA) with a condition and/or symptoms (e.g., cardiovascular, metabolic, renal, pulmonary, neuropsychiatric)⁶; OR
 - o 15-29.9 events per hour (moderate OSA)⁷; **OR**
 - Greater than or equal to 30 events per hour (severe OSA)^Z; OR
 - Preoperative preparation that is intended to improve or optimize the patient's perioperative physical status⁸; OR
 - Persons aged 1–17 years with **ALL** of the following:
 - AHI or REI is ANY of the following⁹⁻¹⁰:

- 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
- o 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 treatment¹¹; OR
 - Persistent OSA with ANY of the following (including post-adenotonsillectomy)¹²:
 - 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 following¹³:
 - A CPAP device is to be used nightly¹³; AND
 - ALL of the following¹⁴:

- 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 15:
 - 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 nightly¹⁶; OR
 - Chronic obstructive pulmonary disease (COPD) for ALL of the following:
 - ANY of the following:
 - Prevention of acute respiratory acidosis (normal or elevated arterial CO₂ tension [PaCO₂] with normal pH)^{Z,17}; OR
 - Prevention of endotracheal intubation and invasive mechanical ventilation in a patient with mild to moderate acidosis and respiratory distress, with the aim of preventing deterioration to a point when invasive ventilation would be considered¹⁷; OR
 - An alternative to invasive ventilation in a patient with severe acidosis and more severe respiratory distress¹⁷; OR
 - The patient has sleep-associated hypoventilation (nocturnal hypoxemia); AND

- A BiPAP device is to be used nightly; OR
- Obesity hypoventilation syndrome (OHS) with ALL of the following:
 - **ANY** of the following:
 - For the initial treatment of a stable ambulatory adult patient with OHS¹⁸; 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
- Progressive neuromuscular disease with ALL of the following¹⁹:
 - 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; OR
- Thoracic cage abnormality with ALL of the following:
 - ANY of the following²⁰:
 - 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; AND
 - A BiPAP device is to be used nightly; OR

- Either a heated or non-heated humidifier is considered medically necessary for use with BiPAP or CPAP; OR
- For continued coverage of BiPAP or CPAP beyond the initial 90-day period, with ALL of the following:
 - Documentation stating that a re-evaluation demonstrated improvement by the patient and continued use will likely provide additional improvement; 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 nights²¹; AND
 - O 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:
 - The appliance has reached a 5-year reasonable useful lifetime (RUL)²²; 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**²³:

- The need for intubation; OR
- Encephalopathy or altered mental status; OR
- Hemodynamic instability; OR
- Facial trauma or facial defects; OR
- Airway obstruction secondary to a mass; OR
- Anticipated need for prolonged mechanical ventilation; OR
- Gastrointestinal bleeding.

Definitions

Apnea Hypopnea Index (AHI): number of apneas and hypopneas per total sleep time⁵

Respiratory Disturbance Index (RDI): number of apneas and hypopneas and respiratory effort-related arousals (RERAs) per total sleep time⁵

Respiratory Event Index (REI): number of apneas and hypopneas per monitoring time⁵

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	

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.²⁴

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).²⁵

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.²⁶

References

- Patel BK. Noninvasive positive pressure ventilation (NIPPV). Revised 2024. https://www.merckmanuals.com/professional/critical-care-medicine/respiratory-failure-and-mechanical-ventilation/noninvasive-positive-pressure-ventilation-nippy
- American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Position statement: Treatment of obstructive sleep apnea. Updated June 9, 2021. https://www.entnet.org/resource/position-statement-treatment-of-obstructive-sleep-apnea/
- 3. Yeghiazarians Y, Jneid H, Tietjens JR, et al. Obstructive sleep apnea and cardiovascular disease: A scientific statement from the American Heart Association. *Circulation*. 2021 Jul 20;144(3):e56-e67. doi:10.1161/CIR.0000000000000988
- 4. Qaseem A, Holty JEC, Owens DK, et al. Management of obstructive sleep apnea in adults: A clinical practice guideline from the American College of Physicians. *Ann Intern Med.* 2013 Oct 1;159(7):471-83. doi:10.7326/0003-4819-159-7-201310010-00704
- 5. Goyal M, Johnson J. Obstructive sleep apnea diagnosis and management. *Mo Med.* 2017 Mar-Apr;114(2):120-124. PMID: 30228558.
- National Institute for Health and Care Excellence (NICE). Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s (NG202). Published August 20, 2021. https://www.nice.org.uk/guidance/ng202
- Patil SP, Ayappa IA, Caples SM, et al. Treatment of adult obstructive sleep apnea with positive airway pressure: An American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2019 Feb 15;15(2):335-343. doi:10.5664/jcsm.7640
- 8. American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Obstructive Sleep Apnea. Practice guidelines for the perioperative management of patients with obstructive sleep apnea: An updated report by the American Society of

- Anesthesiologists Task Force on Perioperative Management of patients with obstructive sleep apnea. *Anesthesiology*. 2014 Feb;120(2):268-86. doi:10.1097/ALN.0000000000000053
- 9. Kang M, Mo F, Witmans M, et al. Trends in diagnosing obstructive sleep apnea in pediatrics. *Children (Basel)*. 2022 Feb 24;9(3):306. doi:10.3390/children9030306
- 10. Savini S, Ciorba A, Bianchini C, et al. Assessment of obstructive sleep apnoea (OSA) in children: An update. *Acta Otorhinolaryngol Ital*. 2019 Oct;39(5):289-297. doi:10.14639/0392-100X-N0262
- Ehsan Z, Ishman SL, Soghier I, et al. Management of persistent, post-adenotonsillectomy obstructive sleep apnea in children: An official American Thoracic Society clinical practice guideline. Am J Respir Crit Care Med. 2024 Feb 1;209(3):248–261. doi:10.1164/rccm.202310-1857ST
- 12. Marcus CL, Brooks LJ, Draper KA, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. 2012 Sep;130(3):e714-55. doi:10.1542/peds.2012-1672
- 13. Anttalainen U, Tenhunen M, Rimpilä V, et al. Prolonged partial upper airway obstruction during sleep an underdiagnosed phenotype of sleep-disordered breathing. *Eur Clin Respir J.* 2016 Sep 6;3:31806. doi:10.3402/ecrj.v3.31806
- 14. Tufik SB, Pires GN, Palombini L, et al. Prevalence of upper airway resistance syndrome in the São Paulo Epidemiologic Sleep Study. *Sleep Med*. 2022 Mar:91:43-50. doi:10.1016/j.sleep.2022.02.004
- 15. Aurora RN, Chowdhuri S, Ramar K, et al. The treatment of central sleep apnea syndromes in adults: Practice parameters with an evidence-based literature review and meta-analyses. Sleep. 2012 Jan 1;35(1):17-40. doi:10.5665/sleep.1580
- 16. Aurora RN, Bista SR, Casey KR, et al. Updated adaptive servo-ventilation recommendations for the 2012 AASM guideline: The treatment of central sleep apnea syndromes in adults: Practice parameters with an evidence-based literature review and meta-analyses. J Clin Sleep Med. 2016 May 15;12(5):757-61. doi:10.5664/jcsm.5812

- Rochwerg B, Brochard L, Elliott MW, et al. Official ERS/ATS clinical practice guidelines: Noninvasive ventilation for acute respiratory failure. *Eur Respir J.* 2017 Aug 31;50(2):1602426. doi:10.1183/13993003.02426-2016
- Mokhlesi B, Masa JF, Brozek JL, et al. Evaluation and management of obesity hypoventilation syndrome: An official American Thoracic Society clinical practice guideline. Am J Respir Crit Care Med. 2019 Aug 1;200(3):e6-e24. doi:10.1164/rccm.201905-1071ST
- Khan A, Frazer-Green L, Amin R, et al. Respiratory management of patients with neuromuscular weakness: An American College of Chest Physicians clinical practice guideline and expert panel report. *Chest*. 2023 Aug;164(2):394-413. doi:10.1016/j.chest.2023.03.011
- 20.Centers for Medicare and Medicaid Services (CMS). Local coverage determination (LCD): Respiratory assist devices (L33800). Revision Effective Date January 1, 2024. https://www.cms.gov/medicare-coverage-database/search.aspx
- 21. Qiao M, Xie Y, Wolff A, et al. Long term adherence to continuous positive airway pressure in mild obstructive sleep apnea. *BMC Pulm Med*. 2023 Sep 1;23(1):320. doi:10.1186/s12890-023-02612-3
- 22. Noridian Healthcare Solutions. Reasonable useful lifetime (RUL) explained. Updated September 13, 2023. https://med.noridianmedicare.com/web/jddme/article-detail/-/view/2 230715/reasonable-useful-lifetime-rul-explained
- 23. Schönhofer B, Kuhlen R, Neumann P, et al. Clinical practice guideline: Non-invasive mechanical ventilation as treatment of acute respiratory failure. *Dtsch Arztebl Int*. 2008 Jun;105(24):424-33. doi:10.3238/arztebl.2008.0424
- 24. Patil SP, Billings ME, Bourjeily G, et al. Long-term health outcomes for patients with obstructive sleep apnea: Placing the Agency for Healthcare Research and Quality report in context-a multisociety commentary. *J Clin Sleep Med*. 2024 Jan 1;20(1):135-149. doi:10.5664/jcsm.10832
- 25. Masa JF, Mokhlesi B, Benítez I, et al. Echocardiographic changes with positive airway pressure therapy in obesity hypoventilation syndrome:

- Long-term Pickwick randomized controlled clinical trial. *Am J Respir Crit Care Med.* 2020 Mar 1;201(5):586-597. doi:10.1164/rccm.201906-11220C
- 26. Wang Z, Wilson M, Dobler CC, et al. AHRQ technology assessments: Noninvasive positive pressure ventilation in the home [internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2019 Mar 14. PMID: 32101390; Bookshelf ID: NBK554171.

Clinical Guideline Revision History/Information

Original Date: February 13, 2025			
Review History			
Version 2	05/01/2025	Added indication and codes (E0561 E0562) for heated and non-heated humidifiers: "Either a heated or non-heated humidifier is considered medically necessary for use with BiPAP or CPAP". Removed 2 bullets for "replacement of the current PAP device": • Change in the structure of the patient's mouth; • The appliance is worn due to excessive use and is unable to be repaired. Added indication for replacement of either a heated or non-heated humidifier for use with BiPAP or CPAP.	