Molina Clinical Policy
Expiratory Positive Airway Pressure (EPAP) for Obstructive Sleep Apnea: Policy No. 145

Last Approval: 10/09/2024
Next Review Due By: October 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Obstructive Sleep Apnea (OSA) is a breathing disorder that is defined by a decrease or complete cessation of airflow during sleep. Airflow obstruction arises when the muscles in the back of the throat fail to keep the airway open. OSA is characterized by repetitive pauses in breathing during sleep, despite the effort to breathe, and is usually associated with a reduction in blood oxygen saturation and is often portrayed by loud snoring, gasping, or choking, and by hypopnea or apnea during sleep. These pauses in breathing, called apneas, typically last 20 to 40 seconds. Hypopnea involves episodes of overly shallow breathing or an abnormally low respiratory rate. Hypopnea differs from apnea in that there remains some flow of air. Untreated OSA is associated with symptoms of sleep deprivation and excessive sleepiness, cognitive dysfunction, diminished quality of life and productivity, sexual dysfunction, mood changes, increased accident risk, and cardiovascular disease and stroke (Malhotra & Kundel 2024; Kline 2023; Schulman 2023).

The results of polysomnogram testing are reported in terms of the apnea-hypopnea index (AHI) or respiratory disturbance index. The AHI is determined by adding the total number of apneas and hypopneas during the sleep time and dividing that number by the total hours of sleep. The respiratory disturbance index has been used synonymously with AHI. In addition to the number of apnea and hypopnea episodes, the respiratory disturbance index also includes the number of respiratory effort-related arousals. The severity of OSA is based on polysomnogram results with an AHI or respiratory disturbance index greater than or equal to 5 and less than 15 indicating mild OSA, an AHI or respiratory disturbance index greater than or equal to 15 and less than or equal to 30 indicating moderate OSA, and an AHI or respiratory disturbance index greater than 30 indicating severe OSA (Kryger et al. 2021; Paruthi 2021; Badr 2021).

Treatment of OSA includes behavioral therapy (e.g., weight loss), drug therapy, continuous positive airway pressure (CPAP), oral appliances, palatal implants, and surgery. CPAP is the first-line treatment for patients with moderate to severe OSA, with a treatment success rate of nearly 100% when used properly. CPAP provides a constant flow of air delivered through a face mask worn while sleeping to keep the upper airway open; patients frequently complain of the intrusive nature of the device, resulting in lack of acceptance or partial adherence (Malhotra & Kundel 2024).

Expiratory Positive Airway Pressure (EPAP) uses an air-valve-type of device that is placed over each nostril. Small exit holes in the device provide a positive airway pressure, also known as a back pressure, which pushes backward into the patient's airway to maintain it open as the patient exhales. EPAP refers to positive airway pressure caused by the patient's own expiration of air. EPAP is currently provided by three devices that have similar functions. Each EPAP device is designed to treat mild to moderate OSA and is typically prescribed by a sleep medicine specialist and is used at home by the patient (Hayes 2023).

Regulatory Status

The United States Food and Drug Administration (FDA) Center for Devices and Radiological Health classified the Provent Sleep Apnea Therapy (Ventus Medical Inc.) as an intranasal expiratory resistance valve for OSA on December 2, 2010, and is regulated as a Class II device (FDA 2010). According to the Provent Therapy website, all Provent Sleep Apnea Therapy devices were discontinued as of June 1, 2020 (Provent Therapy 2020).

Additional EPAP devices that have received FDA approval include the Bongo Rx (AirAvant Medical) and ULTepap™

(Bryggs Medical) (FDA 2018; FDA 2020). The Bongo and ULTepap™ devices are approved for the treatment of mild to moderate OSA in adults that weigh > 66 pounds. The Bongo Rx is designed to be used with headgear similar to nasal pillows that are used with a traditional CPAP machine and tubing. The ULTepap™ may be used with or without headgear. All intranasal expiratory resistance valves are listed under product code "OHP" in the FDA 510(k) database.

COVERAGE POLICY

Nasal expiratory positive airway pressure devices (e.g., Provent, Bongo Rx, ULTepap™) are considered **experimental, investigational, and unproven.** There is insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect for treating obstructive sleep apnea.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Results from early studies indicate that therapeutic response was variable among participants and small sample sizes. Further research from larger, well-designed studies is needed to evaluate the effectiveness of the device compared with established treatments for OSA, to determine its long-term effectiveness and to determine which patients would benefit from this therapy. More recently, Liu et al. (2019) published a study on the efficacy and safety of EPAP with results showing there were no considerable differences between the use of EPAP and CPAP. Below is a summary of relevant studies and trials.

Randomized Controlled Trials

Kureshi et al. (2014) conducted a small randomized, double-blind, placebo-controlled, crossover pilot study. Candidates ages 8-16 years underwent nasal EPAP and placebo polysomnograms. In conclusion, EPAP devices are a potential alternative therapy for obstructive sleep apnea in a small subset of children. Due to variability in individual responses, efficacy of EPAP should be evaluated with polysomnogram.

Berry et al. (2011) performed a prospective, multicenter, sham-controlled, parallel-group, randomized, double-blind clinical trial to investigate the efficacy of nasal EPAP device as a treatment for OSA. The trial included individuals with OSA and a pre-study AHI ≥10/hour were included. Treatment with a nasal EPAP device (N=127) or similar appearing sham device (N=123) for 3 months was completed. Polysomnography was performed on 2 non-consecutive nights (random order: device-on, device-off) at week one and after three months of treatment. Analysis of an intention at week one found the median AHI value (device-on versus device-off) was significantly lower with EPAP. The decrease in the AHI (median) was greater for the intention to treat group. At month three, the percentage decrease in the AHI was 42.7% (EPAP) and 10.1% (sham), P<0.0001. Over three months of EPAP treatment, the Epworth Sleepiness Scale decreased, and the median percentage of reported nights used (entire night) was 88.2%. The authors concluded that the nasal EPAP device significantly reduced the AHI and improved subjective daytime sleepiness compared to the sham treatment in patients with mild to severe OSA with excellent adherence.

Systematic Reviews and Meta-Analyses

Riaz et al. (2015) performed a systematic review and meta-analysis to quantify the effectiveness of nasal EPAP devices as treatment for OSA. Eighteen studies (920 patients) were included. Pre- and post-nasal EPAP for AHI in 345 patients decreased from 27.32 ± 22.24 to 12.78 ± 16.89 events/hour (relative reduction = 53.2%). Nasal EPAP reduced AHI by 53%, oxygen desaturation index by 41% and improved lowest oxygen saturation by three oxygen saturation points. There were no clear characteristics (e.g., demographic factors, medical history, physical exam finding) that predicted favorable response to these devices. Limited evidence suggests that high nasal resistance could be associated with treatment failure. Additional studies are needed to identify demographic and polysomnographic characteristics that would predict therapeutic success with nasal EPAP.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Rossi et al. (2013) evaluated the efficacy of the Provent nasal device for preventing the recurrence of OSA following CPAP withdrawal among 67 patients with OSA who were receiving CPAP. The goal of the study was to determine if OSA patients could occasionally substitute the Provent device for CPAP. For the Active Provent vs. Placebo Provent groups, primary outcomes included OSA severity, oxygen desaturation index, AHI, and Epworth Sleepiness Scale score. Secondary outcomes for the Active Provent vs. Placebo Provent groups included: oxygen desaturation index from ambulatory pulse oximetry and blood pressure. For the CPAP vs. Active Provent groups, or CPAP vs. Placebo Provent groups, secondary outcomes included oxygen desaturation index, AHI, Epworth Sleepiness Scale, and blood pressure. Compliance was assessed using patient diaries and CPAP usage data was downloaded from the devices. OSA recurred in the Provent (oxygen desaturation index 35.8, SD 17.4) and placebo Provent (oxygen desaturation index28.2, SD 18.3) groups. There was no significant difference in oxygen desaturation index, AHI, and Epworth Sleepiness Scale between the Provent and Placebo Provent groups at two weeks. ODI from ambulatory pulse-oximetry and blood pressure at two weeks were not different in the Provent vs. Placebo Provent groups. Oxygen desaturation index, AHI, and blood pressure were significantly higher in the Provent and Placebo Provent groups compared with the CPAP group. In conclusion, Provent cannot be recommended as an alternative short-term therapy for patients with moderate to severe OSA already using CPAP.

Kryger et al. (2011) conducted a prospective, multicenter, single-arm, open-label extension to a three-month EPAP vs sham randomized clinical trial performed by Berry et al. (2011). The goal was to evaluate the long-term durability of treatment response and safety of a nasal EPAP device used to treat OSA. The trial included OSA patients in the EPAP arm of the EPAP vs. sham randomized study who used the EPAP device. Inclusion criteria was defined as use of an EPAP device ≥ four hours per night and ≥ 5 nights per week on average during months one- and two- of the three-month trial. Participants also had to have a ≥ 50% reduction in AHI or AHI reduction to <10 when comparing the three-month device-on polysomnogram to the week one device-off polysomnogram. Treatment with a nasal EPAP device (N = 41) was performed for 12 months. Of the 51 patients eligible, 34 were still using the EPAP device at the end of 12 months. Median AHI was reduced from 15.7 to 4.7 events/h (week 1 device-off versus month 12 device-on). The median decrease in the AHI was 71%. The median proportion of sleep time with snoring was reduced by 74%. Over 12 months of EPAP treatment, the Epworth Sleepiness Scale decreased, and the median percentage of reported nights used (entire night) was 89%. In conclusion, nasal EPAP significantly reduced the AHI, improved subjective daytime sleepiness, and reduced snoring after 12 months of treatment. Long-term adherence to EPAP was excellent in those who had a positive clinical response at month three of the EPAP vs. sham study.

Walsh et al. (2011) evaluated tolerability, short-term efficacy, and adherence of an EPAP nasal device in 59 OSA patients who refused CPAP or used CPAP less than 3 hours per night. After demonstrating tolerability to the EPAP device during approximately one week of home use, 47 patients (80%) underwent a screening/baseline polysomnogram, forty-three patients met AHI entry criteria and underwent a second polysomnogram within 10 days of the first polysomnogram. Twenty-four patients (56%) met pre-specified efficacy criteria and underwent a third polysomnogram which was performed after 5 weeks of EPAP treatment. Compared to the first polysomnogram, mean AHI was significantly lower at both the second and third polysomnograms. For most patients, AHI at the third polysomnogram was similar to the AHI at the second polysomnogram. Device use was reported an average of 92% of all sleep hours. Improvements in AHI and Epworth Sleepiness Scale scores were noted combined with the high degree of treatment adherence observed. 3his suggests that the EPAP device tested may a useful therapeutic option for OSA. Limitations of the study include lack of randomization and control, small sample size and short-term follow-up; a potential for bias exists due to manufacturer sponsorship of the study.

Patel et al. (2011) studied a one-way nasal device at the New York University Sleep Disorders Center, using EPAP to identify appropriate patients for treatment. Pilot data provided potential mechanisms of action. Twenty patients with OSA underwent three nocturnal polysomnograms including diagnostic, therapeutic (with a Provent® nasal valve device), and CPAP. Nineteen of the 20 patients tolerated the device. The nasal valve device produced improvement in sleep disordered breathing in 75% of patients with OSA of varying severity with approximately 50% of patients reaching a clinically significant reduction in the respiratory disturbance index. While the study was not able to establish predictors of success or a definitive mechanism of action, it helped define a restricted list of candidates for further investigation. A potential for bias exists due to manufacturer sponsorship of the study.

Rosenthal et al. (2009) performed a multicenter, prospective study of nasal EPAP device in the treatment of OSA. Study objectives were to evaluate the efficacy of a novel device placed in the nares that imposes an expiratory

resistance for the treatment of OSA and evaluate adherence to the device over a 30-day in-home trial period. Participants reported using the device all night long for 94% of nights during the in-home trial. The authors concluded that treatment was well tolerated and accepted by participants. An overall reduction in AHI was documented however, therapeutic response was variable. Further research is required to identify ideal candidates for this therapeutic option.

Colrain et al. (2008) performed the first study using the Provent device for the treatment of OSA and was conducted at the Stanford Research Institute International. Thirty men and women were recruited for the study. Twenty-four had at least mild OSA (AHI >5) and six were primary snorers. Participants underwent two nights of polysomnographic evaluation, one with and one without the Provent device (with the order of nights counterbalanced across participants). Standard polysomnogram was conducted to compare participants sleep both with and without the device, with the scoring conducted blind to treatment condition. Measurement of AHI and oxygen desaturation indices both significantly decreased, and the percentage of the night spent above 90% oxygen saturation significantly increased with device use. Results of this pilot study are suggestive of a therapeutic effect of expiratory nasal resistance for some OSA patients and indicate that this technique is worthy of further clinical study. A potential for bias exists due to manufacturer sponsorship of the study.

National and Specialty Organizations

The 2019 **American Academy of Sleep Medicine (AASM)** guidelines issued two practice statements for appropriate and effective management of patients with OSA treated with positive airway pressure ([1-2]Patil et al. 2019):

1. OSA treatment with positive airway pressure therapy should be based on a diagnosis of OSA which is confirmed by objective sleep apnea testing; and
2. Adequate follow-up should include monitoring objective efficacy and device data to confirm treatment and adherence; this should happen after initiation of positive airway pressure therapy and during OSA treatment.

AASM also provided the following recommendations:

1. Positive airway pressure should be used, compared to no therapy, for treatment of OSA in adults with excessive sleepiness, impaired sleep-related quality of life, or comorbid hypertension.
2. Positive airway pressure therapy can begin using automatic positive airway pressure therapy at home or in-laboratory positive airway pressure titration in adults with OSA and no significant comorbidities.
3. CPAP or automatic positive airway pressure is recommended for ongoing treatment of OSA in adults.
4. CPAP or automatic positive airway pressure over bilevel positive airway pressure is recommended as the routine treatment of OSA in adults.
5. Educational interventions should be given at the start of positive airway pressure therapy in adults with OSA.
6. Behavioral interventions should be given during the onset of positive airway pressure therapy in adults with OSA.
7. Telemonitoring-guided interventions are recommended during the onset of positive airway pressure therapy in adults with OSA.

The **World Sleep Society (WSS)** International Sleep Medicine Guidelines Committee published an endorsement of the AASM 2019 guidelines in 2022 (Jacobowitz et al. 2022).

The **American College of Physicians (ACP)** published the clinical practice guideline *Management of Obstructive Sleep Apnea in Adults* with the following recommendations (Qaseem et al. 2013):

1. Patients who are overweight and obese with a diagnosis of OSA should be encouraged to lose weight.
2. CPAP treatment is an initial therapy for patients with OSA.
3. Mandibular advancement devices are considered an alternative therapy to CPAP treatment for patients with OSA with a preference to these types of devices. The devices may also be considered for patients with adverse effects due to CPAP treatment.

SUPPLEMENTAL INFORMATION

Apnea Hypopnea Index (AHI): The number of apneas plus the number of hypopneas during the entire sleeping period, times 60, divided by total sleep time in minutes; unit: event per hour (AASM 2023).

The American Academy of Sleep Medicine provides the following updated definitions of OSA severity (AASM

2023):

- Mild OSA: AHI of 5-15, involuntary sleepiness during activities that require little attention, such as watching TV or reading.
- Moderate OSA: AHI of 15-30, involuntary sleepiness during activities that require some attention, such as meetings or presentations.
- Severe OSA: AHI > 30: involuntary sleepiness during activities that require more active attention, such as talking or driving.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
94799	Unlisted pulmonary service or procedure (when used for EPAP)

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
A7049	Expiratory positive airway pressure intranasal resistance valve

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/09/2024	Policy reviewed, no changes to criteria.
12/13/2023	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, Supplemental Information, and References. IRO Peer Review on October 31, 2023 by a practicing, board-certified physician with specialties in Neurology and Sleep Medicine.
12/14/2022	Policy reviewed, no changes to the criteria, references updated.
12/08/2021	Policy reviewed, no changes to coverage criteria. Summary of Medical Evidence section condensed; updated AASM and AAP guidelines. References updated.
12/09/2020	Policy reviewed, no changes to the criteria.
12/10/2019	Policy reviewed, no changes to the criteria. No new evidence-based studies or guidelines found. IRO Peer Review. Policy reviewed on October 25, 2019, by a practicing, board-certified physician in Sleep Medicine.
07/10/2018	Policy reviewed, no changes to the criteria.
09/19/2017	Policy reviewed, no changes to the criteria.
11/08/2016	Policy reviewed, no changes to the criteria. Summary of Medical Evidence and Reference sections updated.
12/16/2015	Policy reviewed, no changes to the criteria.

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