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

Last Approval: 10/14/2026
Next Review Due By: October 2027

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. References included were accurate at the time of policy approval and publication.

OVERVIEW

Obstructive sleep apnea (OSA) is a breathing disorder defined by a decrease or complete cessation of airflow during sleep, which arises when the muscles in the back of the throat fail to keep the airway open. OSA is characterized by repetitive obstructive respiratory events during sleep despite the effort to breathe, is usually associated with a reduction in blood oxygen saturation, and is often characterized by loud snoring, gasping, or choking. These respiratory events include apneas, which are complete cessations of airflow for ≥ 10 seconds, or hypopneas, which are partial reductions in airflow associated with oxygen desaturation or arousal. 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, cardiovascular disease, and stroke. OSA is not a clinical diagnosis and requires objective testing, such as an in-laboratory polysomnogram or unattended home sleep apnea test (Kline 2026; Malhotra & Kundel 2026; Schulman 2026).

The results of polysomnogram testing may be reported with the apnea-hypopnea index (AHI), degree of hypoxemia, respiratory disturbance index (RDI), or other variables. The AHI is determined by adding the total number of apneas and hypopneas and dividing that number by the total hours of sleep. The RDI is similar but includes respiratory effort-related arousals (RERAs), which are events that do not meet the criteria for apneas or hypopneas. While RDI has a greater degree of interobserver variability than AHI and the scoring of RERAs are not required by the American Academy of Sleep Medicine (AASM), many sleep laboratories choose to report RDI as RERAs disrupt sleep and may increase the risk for neurocognitive dysfunction. The severity of OSA is based on polysomnogram results, with an AHI or RDI between 5 and 14 indicating mild OSA, between 15 and 30 indicating moderate OSA, and greater than 30 indicating severe OSA (Kline 2026; Schulman 2026).

Treatment options for OSA may include behavioral modification (e.g., weight loss, avoidance of alcohol and sedatives, altered sleep position for patients with positional OSA), continuous positive airway pressure (CPAP), oral appliances, neuromuscular electrical stimulation, and bariatric surgery or pharmacologic therapy for weight loss. CPAP is the first-line treatment for patients with moderate to severe OSA, and the AASM recommends offering PAP therapy to all patients diagnosed with OSA. CPAP provides a constant flow of air, delivered through a full-face, nasal, or nasal pillow mask, to keep the upper airway open. However, nonadherence or suboptimal adherence is common due to the intrusive nature of the device (Malhotra & Kundel 2026).

Nasal expiratory positive airway pressure (EPAP), also called expiratory resistance valves, are a type of intranasal device for snoring and OSA. Small nasal inserts are placed over or just inside the nostrils, which contain one-way valves that remain open during inhalation and partially close during exhalation, creating expiratory resistance to help maintain upper airway patency and prevent collapse during subsequent inhalation. One benefit of nasal EPAP devices is that they do not require electricity, external machines, or tubing, and may be helpful for patients who are unable to tolerate or afford CPAP therapy. Nasal EPAP devices are typically designed to treat mild to moderate OSA and are designed for closed mouth breathing only (Sleeper et al. 2022).

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Regulatory Status

Nasal EPAP devices are typically regulated by the FDA as intranasal, expiratory resistance devices for OSA, and as Class II medical devices cleared through the 510(k) premarket notification process under product code OHP. Such devices include *Bongo Rx* (AirAvant Medical/InnoMed Healthscience) and *ULTepap* (Bryggs Medical), which are indicated for use in the treatment of mild to moderate OSA in adults > 66 lbs. *Provent* (Ventus Medical), one of the first FDA-cleared devices in this category, was discontinued in June 2020 and is no longer marketed. Other devices, such as OptiPillows EPAP Mask (Cpapnea Medical Supply) and Theravent (Ventus Medical), have been FDA-cleared for snoring only, and are regulated as nasal dilators and Class I devices under product code LWF. These devices, despite being described as "EPAP masks" by the manufacturer, are intended to reduce and eliminate snoring only, and some have received warning letters from the FDA due to misbranding, and false or misleading labeling that indicate the device treats OSA (FDA 2020).

COVERAGE POLICY

Nasal expiratory positive airway pressure (EPAP) devices (e.g., Bongo Rx, ULTepap) for obstructive sleep apnea (OSA) are considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

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

Randomized Controlled Trials

Wheeler et al. (2016) conducted a randomized, controlled, two-period crossover trial to evaluate the effectiveness and tolerability of nasal expiratory positive airway pressure (EPAP) as an alternative to continuous positive airway pressure (CPAP) for treating obstructive sleep apnea (OSA) in acute ischemic stroke patients. OSA is common after stroke and predicts poor outcomes, and CPAP is generally poorly tolerated by stroke patients. It's also important to note that nasal EPAP was compared to untreated OSA, and the study did not include a CPAP arm. Nineteen participants (n = 19) underwent one night with EPAP and one night without EPAP while monitored with a validated device (Watch-PAT 200). The primary outcome was a change in the apnea-hypopnea index (AHI), and secondary outcomes included mean and minimum oxygen saturation, the oxygen desaturation index, and sleep efficiency. Median AHI was 17.1 with EPAP and 25.2 without EPAP, meaning on average, AHI was 5.73 points lower on the EPAP night compared to the control night. However, this difference was not statistically significant (95% CI -14.4 to 2.97, p = 0.183). Sensitivity analysis, which included a subgroup with ≥ 3 hours of EPAP use, showed similar, nonsignificant results. No significant differences were seen for oxygen saturation measures or for sleep efficiency. Most participants reported tolerating EPAP well, with > 75% using it for ≥ 3 hours, although some reported discomfort or difficulty breathing. Study limitations include single-night treatment exposure, absence of long-term efficacy data, reliance on patient self-report for device usage time, use of actigraphy rather than full polysomnography for sleep measurement, and a lack of objective adherence monitoring. The authors concluded that EPAP is likely not an effective alternative to CPAP in acute stroke patients with OSA. (ClinicalTrials.gov NCT01703663).

Kureshi et al. (2014) conducted a randomized, double-blind, placebo-controlled, crossover pilot study to evaluate the efficacy, tolerability, and adherence of nasal EPAP devices for treating moderate-to severe OSA in children aged 8-16 years who were candidates for CPAP but either could not tolerate it or desired an alternative. Fourteen participants (n = 14) completed both nasal EPAP and placebo polysomnograms. Responders were defined as those achieving at least a 50% reduction in AHI or an AHI < 5 during their EPAP study. Responders then used nasal EPAP nightly at home for 30 days with adherence measured by daily check-ins, logs, and collection of used devices. Nasal EPAP use showed statistically significant improvement in the obstructive apnea index (media AHI 0.6 vs. 4.2 for placebo; p = 0.010), but non-significant improvements in AHI, arousal index, and time with oxygen saturation < 90%. Additionally,

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individual responses varied widely. Two participants with severe OSA had large numerical AHI reductions but remained in the severe OSA range, and two participants worsened with EPAP. Older children and those with less hypercapnia on placebo night had better responses to EPAP. Of nine responders, seven completed the home phase, suggesting high adherence (mean 83%), and supported significant improvement in daytime sleepiness, measured by the Epworth Sleepiness Scale, and OSA-related quality of life, measured by the OSA-18 questionnaire. Mild adverse effects included transient discomfort in two participants and mild skin irritation in one participant, with no serious adverse events reported. The authors concluded that nasal EPAP devices may serve as a potential alternative therapy for a small subset of children with persistent OSA after adenotonsillectomy or those unable to tolerate CPAP. However, due to individual variability, the efficacy of nasal EPAP should be confirmed with a polysomnogram before long-term use. Larger-scale studies and studies comparing nasal EPAP directly with CPAP are needed. (ClinicalTrials.gov NCT01768065).

Rossi et al. (2013) conducted a randomized controlled trial to evaluate 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. (ClinicalTrials.gov NCT01332175).

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.

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. (ClinicalTrials.gov NCT00849043).

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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 were reviewed, including two randomized controlled trials, for a total of 920 participants. The primary outcomes were AHI, oxygen desaturation index (ODI), lowest oxygen saturation (LSAT), and Epworth Sleepiness Scale scores. Meta-analysis of 345 patients showed that AHI decreased from 27.32 ± 22.24 to 12.78 ± 16.89 (53.2% relative reduction; mean difference -14.78 [95% CI -19.12 to -10.45], $p < 0.00001$), though heterogeneity and moderate publication bias were present. ODI in 247 patients decreased from 21.2 ± 19.3 to 12.4 ± 14.1 events per hour (41.5% reduction; MD -7.69 [95% CI -11.78 to -3.60], $p = 0.0002$), and LSAT improved in 146 patients from 83.2% ± 6.8% to 86.2% ± 11.1% (MD +3% [95% CI 0.57-5.63%], $p = 0.002$). While no major adverse effects were reported, up to 42% of patients experienced minor adverse effects such as difficulty breathing or exhaling, nasal congestion, dry mouth, insomnia, or headache. There were no clear characteristics (e.g., demographic factors, medical history, physical exam finding) that predicted a favorable response to nasal EPAP devices. Limited evidence suggests that high nasal resistance could be associated with treatment failure. Efficacy was variable across studies, with some (e.g., Rossi et al. 2013) showing high residual AHI and lack of benefit, particularly in patients who had withdrawn from CPAP. Study limitations included variable follow-up, exclusion of patients with severe comorbidities, small sample sizes, frequent reliance on industry funding, and the exclusion of many median-reported datasets from pooled analyses. The authors concluded that nasal EPAP does not eliminate OSA; however, it does improve AHI, ODI, LSAT, and subjective sleepiness, with high portability, ease of use, and no major complications. For these reasons, nasal EPAP might be an alternative for certain OSA patients intolerant to PAP, for those with mild or positional OSA without comorbidities, or for people in unusual circumstances (e.g. no electricity). Further research is needed to establish long-term efficacy and identify patients most likely to benefit from nasal EPAP.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

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.

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 (PAP) ([1-2]Patil et al. 2019):

1. OSA treatment with PAP 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 PAP therapy and during OSA treatment.

AASM also provided the following recommendations ([1-2]Patil et al. 2019):

1. PAP 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. PAP 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 PAP is recommended for ongoing treatment of OSA in adults.

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4. CPAP or automatic PAP 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 PAP therapy in adults with OSA.
6. Behavioral interventions should be given during the onset of PAP therapy in adults with OSA.
7. Telemonitoring-guided interventions are recommended during the onset of PAP therapy in adults with OSA.

The **AASM** Emerging Technology Committee published a supplemental reference and side-by-side comparison of emerging OSA treatment alternatives, which suggests more research is needed to establish safety and efficacy for Class II nasal EPAP devices intended to treat OSA. The authors note that for Bongo Rx, the device is supported by a single-center, open-label, non-randomized, and industry sponsored clinical trial with only 10 participants, and that additional clinical trials with more participants and an improved study design is warranted to evaluate long-term efficacy, acceptance, and patient satisfaction. For ULTepap, the authors note that clinical trials were not performed prior to FDA clearance, and that trials are needed to assess the efficacy, tolerance, and safety of the device. The authors also note that the manufacturer website only provides supporting data from Provent, a previous device on the market from a different manufacturer (Chiang et al. 2021).

The **World Sleep Society (WSS)** International Sleep Medicine Guidelines Committee and Sleep and Breathing Disorders Taskforce published an endorsement of the AASM 2019 guidelines, including the indications for PAP therapy, the use of different types of PAP modalities, and strategies to improve patient outcomes. The WSS emphasized that this endorsement applies to limited geographic regions, and that the guidelines do not address other aspects related to adherence (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 (strong recommendation, but low-quality evidence)
2. CPAP treatment as the initial therapy for patients diagnosed with OSA (strong recommendation with moderate-quality evidence)
3. Mandibular advancement devices are considered an alternative therapy to CPAP treatment for patients with OSA who prefer these types of devices or who experience adverse effects from CPAP treatment (weak recommendation, low-quality evidence)

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)

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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

10/14/2026	Policy reviewed. No changes to coverage criteria.
10/08/2025	Policy reviewed. No changes to coverage criteria.
10/09/2024	Policy reviewed. No changes to coverage criteria.
12/13/2023	Policy reviewed. No changes to coverage criteria. 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 coverage criteria.
12/08/2021	Policy reviewed. No changes to coverage criteria.
12/09/2020	Policy reviewed. No changes to coverage criteria.
12/10/2019	Policy reviewed. No changes to coverage criteria. 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 coverage criteria.
09/19/2017	Policy reviewed. No changes to coverage criteria.
11/08/2016	Policy reviewed. No changes to coverage criteria.
12/16/2015	Policy reviewed. No changes to coverage criteria.

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