**Preface**

This Medical Guidance is intended to facilitate the Utilization Management process. 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 (i.e., 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 exclusions 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 following website: [http://www.cms.hhs.gov/center/coverage.asp](http://www.cms.hhs.gov/center/coverage.asp).

**FDA Indications**

EPAP is a procedure and, therefore, not subject to FDA regulation. However, the medical devices, drugs, and tests used in conjunction with EPAP for the treatment of obstructive sleep apnea may be regulated by the FDA. Provent Sleep Apnea Therapy (Ventus Medical Inc.) is classified by the Center for Devices and Radiological Health (CDRH) as an intranasal expiratory resistance valve for OSA and regulated as a Class II device, classified under the Product Code OHP.  

**Centers for Medicare and Medicaid Services (CMS)**

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

No National Coverage Determination (NCD) for EPAP as a treatment for obstructive sleep apnea was found on the CMS website. There is a NCD for continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea (OSA) (240.4). CPAP is covered when used in adult patients with OSA.

**Initial Coverage Criteria**

Expiratory positive airway pressure (EPAP) devices that include nasal dilators (Provent) are considered experimental and investigational due to insufficient clinical evidence supporting the safety and efficacy for treating obstructive sleep apnea.
Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) is a breathing disorder that is defined by either 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.

The results of polysomnogram (PSG) testing are reported in terms of the apnea-hypopnea index (AHI), or respiratory disturbance index (RDI). 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. RDI has been used synonymously with AHI, in addition to the number of apnea and hypopnea episodes, the RDI also includes the number of respiratory effort-related arousals (RERA). The severity of OSA is based on PSG results; an AHI/RDI greater than or equal to 5 and less than 15 is mild, an AHI/RDI greater than or equal to 15 and less than or equal to 30 is moderate, and an AHI/RDI greater than 30 is severe.

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; however, patients frequently complain of the intrusive nature of the device, resulting in lack of acceptance or partial adherence.

Expiratory positive airway pressure (EPAP)

Expiratory positive airway pressure (EPAP) involves the use of an air-valve-type of device, which is placed over each nostril. Air is easily allowed through the valves when one breathes in, but when one breathes out, small exit holes in the device create a back pressure, called a positive airway pressure, that pushes backward through one’s airway to keep it open. Since this positive airway pressure is created by your own expiration of air, it is called expiratory positive airway pressure. There is currently one device called the Provent (Ventus
Medical Inc.) that is used for EPAP. The device is equipped with small bidirectional valves worn just inside each nostril and secured to the outside of the nose with adhesive. The Provent device is intended for treatment of mild, moderate, and severe obstructive sleep apnea. The device is typically prescribed by a sleep medicine specialist and is used by the patient at home.  

**GENERAL INFORMATION**

**Summary of Medical Evidence**

Overall the quality of the available evidence is low. Results from available studies indicate that therapeutic response is variable among the participants and sample sizes are small. 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.

**EPAP**

Rossi and associates (2013) evaluated the efficacy of the Provent nasal device for preventing the recurrence of OSA following CPAP withdrawal in patients with moderate-to-severe OSA with well-established improvement while on CPAP. The goal of the study was to determine if OSA patients could occasionally substitute the Provent for their CPAP. This study, conducted in outpatient sleep clinics in the United Kingdom and Switzerland, randomized 67 patients with OSA receiving CPAP to 1 of 3 groups for 2 weeks: Continuing CPAP (n=23; mean age 64.4 years), Active Provent (n=22; mean age 63.2 years), or Placebo Provent (n=22; mean age 59.7 years). The three groups were similar at baseline and their mean AHI before CPAP treatment was 38 events per hour. Primary outcomes included for the Active Provent versus Placebo Provent groups were OSA severity (ODI), AHI, and ESS score. Secondary outcomes for the Active Provent versus Placebo Provent groups included ODI from ambulatory pulse oximetry and BP (blood pressure). For the CPAP versus Active Provent, or CPAP versus Placebo Provent groups, secondary outcomes included ODI/AHI, ESS, and BP. Compliance was assessed by patient diaries. CPAP usage data was downloaded from the machines. One patient in the Active Provent group withdrew from the study due to symptom recurrence while 3 patients (1 in the Active Provent group and 2 in the Placebo Provent group) were excluded from the study due to insufficient compliance leaving 63 patients in this per protocol analysis. OSA recurred in the Provent (ODI 35.8, SD 17.4) and placebo Provent (ODI 28.2, SD 18.3) groups, and there was no significant difference in ODI, AHI and ESS between Provent and placebo Provent at 2 weeks (mean difference ODI -1.0, 95% CI -10.0 to +12.0, p=0.85; AHI +3.2, 95% CI -7.7 to +14.1, p=0.52; and ESS -1.4, 95% CI -4.1 to +1.4, p=0.33). ODI from ambulatory pulse-oximetry and BP at 2 weeks were not different in the Provent versus placebo Provent groups. ODI, AHI and BP, but not ESS, were significantly higher in the Provent and placebo Provent groups compared with CPAP. The authors concluded that Provent cannot be recommended as an alternative short-term therapy for patients with moderate to severe OSA already on CPAP.  

Berry and colleagues (2011) performed a prospective, multicenter, sham-controlled, parallel-group, randomized, double-blind clinical trial to investigate the efficacy of nasal expiratory positive airway pressure (EPAP) device as a treatment for obstructive sleep apnea (OSA). Individuals with Obstructive sleep apnea with 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 (PSG) was performed on 2 non-consecutive nights (random order: device-on, device-off) at week 1 and after 3 months of treatment. Analysis of an intention At week 1, the median AHI value (device-on versus device-off) was significantly lower with EPAP (5.0 versus 13.8 events/h, P<0.0001) but not sham (11.6 versus 11.1 events/h, P=NS); the decrease in the AHI (median) was greater (-52.7% vs. -7.3%, P<0.0001) for the ITT group. At month 3, the percentage decrease in the AHI was 42.7% (EPAP) and 10.1% (sham), P<0.0001. Over 3 months of EPAP treatment the Epworth Sleepiness Scale decreased (9.9±4.7 to 7.2±4.2, P<0.0001), and the median percentage of reported nights used (entire night) was 88.2%. to treat group (ITT) (patients completing week 1 PSGs) (EPAP N=119, sham N=110) was performed. 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. 14

Another prospective, multicenter, single-arm, open-label extension to a 3-month EPAP vs sham randomized clinical trial was conducted by Kryger et al (2011). The goal was to evaluate the long-term durability of treatment response and safety of a nasal expiratory positive airway pressure (EPAP) device used to treat obstructive sleep apnea (OSA). The trial included OSA patients in the EPAP arm of the EPAP vs sham randomized study who used the EPAP device ≥4 h per night, ≥5 nights per week on average during months 1 and 2 of the 3-month trial and had ≥50% reduction in AHI or AHI reduction to<10 documented by polysomnography, comparing the 3-month device-on PSG to the week-one device-off PSG. Treatment with a nasal EPAP device (N = 41) for 12 months was performed. Polysomnography (PSG) on the patients wearing the device was performed after 12 months of treatment. The month 12 device-on PSG data from the analyzable subject cohort (N = 34) was compared to the week 1 device-off PSG from the EPAP vs sham trial. 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 decrease in the AHI (median) was 71.3% (p<0.001). The median proportion of sleep time with snoring was reduced by 74.4% (p<0.001). Over 12 months of EPAP treatment, the Epworth Sleepiness Scale decreased (11.1±4.2 to 6.0±3.2, p<0.001), and the median percentage of reported nights used (entire night) was 89.3%. The authors concluded that 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 3 of the EPAP vs sham study. 15

Walsh et al. (2011) evaluated tolerability, short-term efficacy and adherence of an expiratory positive airway pressure (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 1 week of home use, 47 patients (80%) underwent a baseline polysomnogram (PSG1). Forty-three patients met AHI entry criteria and underwent PSG2 within 10 days of PSG1. Twenty four patients (56%) met pre-specified efficacy criteria and underwent PSG3 after 5 weeks of EPAP treatment. Compared to PSG1, mean AHI was significantly lower at both PSG2 and PSG3. For most patients AHI at PSG3 was similar to AHI at PSG2. Device use was reported an average of 92% of all sleep hours. The authors concluded that improvements in AHI and Epworth Sleepiness Scale (ESS) scores, combined with the high degree of treatment adherence observed, suggest that the EPAP device tested
may become 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. 19

At the New York University Sleep Disorders Center, Patel et al. (2011) studied a one way nasal device using expiratory positive airway pressure (EPAP) to identify appropriate patients for the therapy and provide pilot data as to its potential mechanisms of action. Twenty patients with OSA underwent three nocturnal polysomnograms (NPSG) including diagnostic, therapeutic (with a Provent® nasal valve device) and CPAP. Nineteen of the 20 patients tolerated the device. The authors reported that the nasal valve device produced improvement in sleep disordered breathing in 75% of patients with OSA of varying severity, with 50% of patients reaching a clinically significant reduction in RDI. Although the study was not able to establish predictors of success or a definitive mechanism of action, the authors thought that it helps define a restricted list of candidates for further investigation. A potential for bias exists due to manufacturer sponsorship of the study. 21

Rosenthal and colleagues (2009) performed another multicenter, prospective study of nasal EPAP device in the treatment of obstructive sleep apnea: Efficacy and 30-day adherence. Study objectives were to evaluate the efficacy of a novel device placed in the nares that imposes an expiratory resistance for the treatment of obstructive sleep apnea (OSA) and evaluate adherence to the device over a 30-day in-home trial period. Design: One diagnostic and 3 treatment polysomnograms were administered in a Latin-square design to identify the optimal expiratory resistance to be used during the 30-day in-home trial. Subjects had repeat polysomnography with the prescribed device at the end of the 30-day trial. Setting: Multicenter study. Participants included (N = 34; age 27 to 67) with a baseline apnea-hypopnea index (AHI) >= 5. The AHI was reduced from 24.5 +/- 23.6 (mean +/- SD) to an average of 13.5 +/- 18.7 (p < 0.001) across initial treatment nights. The AHI was 15.5 +/- 18.9 (p = 0.001) for the prescribed device at the end of the 30-day trial. Of 24 subjects with an AHI > 10 at baseline, 13 achieved an AHI <= 10 on the initial treatment nights; 10 had a similar response on the final treatment night. Percent of the night snoring decreased from 27.5 +/- 23.2 to 11.6 +/- 13.7 (p < 0.001) on initial treatment nights and 14.6 +/- 20.6 (p = 0.013) at the end of the trial; Epworth Sleepiness scores decreased from 8.7 +/- 4.0 at baseline to 6.9 +/- 4.4 (p < 0.001) at the end of the trial; the Pittsburgh Sleep Quality Index improved from 7.4 +/- 3.3 to 6.5 +/- 3.6 (p = 0.042). Mean oxygen saturation increased from 94.8 +/- 2.0 to 95.2 +/- 1.9 (p = 0.023) on initial treatment nights and 95.3 +/- 1.9 (p = 0.003) at the end of the trial. Sleep architecture was not affected. Participants reported using the device all night long for 94% of nights during the in-home trial. The authors concluded that treatment with this novel device was well tolerated and accepted by the participants. An overall reduction in AHI was documented; however, therapeutic response was variable among the participants. Further research is required to identify the ideal candidates for this new therapeutic option in the management of OSA. 16

The first study using the nasal Provent device for the treatment of OSA was conducted at the Stanford Research Institute International by Colrain et al. (2008) to test the hypothesis that the application of expiratory resistance via a nasal valve device would improve breathing during sleep in subjects with OSA and in primary snorers.
Thirty men and women were recruited for the study. Twenty-four had at least mild OSA (AHI > 5), and 6 were primary snorers. Subjects underwent 2 nights of polysomnographic evaluation, one with and one without a new nasal resistance device with the order of nights counterbalanced across participants. The device consisted of a small valve inserted into each nostril calibrated to provide negligible inspiratory resistance, but increased expiratory resistance. Standard polysomnography was conducted to compare participants' sleep both with and without the device, with the scoring conducted blind to treatment condition. The apnea-hypopnea (AHI) and oxygen desaturation (O2DI) indices both significantly decreased and the percentage of the night spent above 90% saturation significantly increased with device use. The 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.

Hayes, Cochrane, UpToDate, MD Consult etc.

Hayes does not have a medical technology directory report on the use of EPAP as a treatment for obstructive sleep apnea. There is a Health Technology Brief on Provent² Sleep Apnea therapy (2013). This report indicates that preliminary evidence from the available studies suggests that use of the Provent nasal device significantly improves the apnea-hypopnea index (AHI) and some other OSA outcomes during short-term and midterm use of the device in patients with mild, moderate, and severe OSA, compared with baseline values. In addition, compared with a sham device, the improvements were more pronounced. Most of the studies evaluated short-term outcomes (~3 months) although 1 small prospective open-label study evaluated outcomes at 12 months of Provent use in patients who complied with treatment in the randomized controlled trial (RCT) on this device. The efficacy of the Provent device has only been compared directly with CPAP in 1 short-term study (2 weeks), and has not been directly compared with other established OSA treatments. The therapeutic response to the Provent device varied among the patients, i.e., approximately 50% or more patients responded to the device, reaching a clinically significant reduction in the AHI, while the other patients did not respond. It is unclear which factors are predictive of treatment response. There was some evidence that the use of the Provent device improved sleep quality and daytime sleepiness among OSA patients, improved the observed amount of snoring, and had no effect on sleep architecture. The device was well tolerated and adherence to the device, evaluated in four studies, was high. In the largest cohort (n=119), device adherence was estimated at almost 90% of full-night use over 3 months. Device adherence was 89% in the prospective study that followed patients for 12 months. There were no serious adverse events related to the use of the device. One study reported a device-related adverse event rate of 45%, which was not confirmed in the other studies. Most adverse events were mild, such as nasal discomfort and dry mouth.

Despite these promising findings, the quality of the evidence was low. Only 2 studies included an appropriate control group, while in the other studies patients served as their own controls. Sample sizes were small, and there were a fair number of dropouts. Additional limitations included the variable use of high- and standard-resistance devices, self-reported adherence data, and a heterogeneous patient population. Overall, there is some evidence to suggest that the Provent nasal device is a safe and efficacious treatment for approximately half of the OSA patient population. However, independent randomized controlled trials are needed to evaluate the effectiveness of the device compared with established treatments for OSA, and to evaluate its long-term
effectiveness particularly in terms of morbidity and mortality related to OSA. Moreover, a better understanding of the clinical profile of patients who most likely benefit from this therapy is required.  

**Cochrane:**

There is evidence that CPAP is effective in reducing sleepiness and improving quality of life in people with moderate or severe OSA. There are no Cochrane reviews that pertain specifically to the use of BPAP or EPAP.

A systematic review of 36 trials involving 1,718 patients analyzed the efficacy of CPAP in the treatment of adults with OSA. It found that CPAP is effective in reducing sleepiness and improving quality-of-life measures in people with moderate and severe OSA. Furthermore, it is more effective than oral appliances in reducing respiratory disturbances in these people, but subjective outcomes are more equivocal. Some people prefer oral appliances to CPAP where both are effective, possibly because appliances offer a more convenient way of controlling OSA. Short-term data indicate that CPAP leads to lower blood pressure than control.  

A systematic review of four trials involving 132 patients compared the efficacy of the various CPAP delivery interfaces available for the treatment of OSA. Because the number of studies comparing various interface types is limited, the optimum CPAP delivery interface remains unclear. The review found, however, that nasal pillows or the Oracle oral mask may be useful alternatives when a patient cannot tolerate conventional nasal masks. The face mask cannot be recommended as a first-line interface, but it may be considered if nasal obstruction or dryness limits the use of a nasal mask.

A systematic review of 45 studies involving 1,874 patients analyzed the efficacy of interventions designed to increase adherence to CPAP. Based on the results of 30 of the studies involving 1,136 patients, the authors concluded that the effect of auto-CPAP in increasing hours of use in unselected patients starting this treatment remains unclear. Different pooled analyses gave conflicting results, and it may be that carefully selected participants may respond more favorably than others. Based on six studies involving 285 patients, the evidence in support of bi-PAP, self-titration, and humidification is lacking, and further studies are required. There was also no significant difference observed with expiratory pressure relief (C-flex) based on six studies involving 318 patients, and conflicting results with humidification based on three studies involving 135 patients. Some evidence indicates that psychological and educational interventions improve CPAP usage. The studies assembled were characterized by high machine use in the control groups and low withdrawal rates, making it less likely that any benefit could be demonstrated.

**UpToDate**

Several reports in UpToDate summarize the general management and treatment of obstructive sleep apnea in adults and children. There are no reports that specifically mention clinical appropriateness of EPAP.

**Professional Organizations**
The American Academy of Sleep Medicine (AASM) 2009 guidelines recommends offering positive airway pressure therapy to all patients who have OSA on the basis of expert consensus. They define OSA as either an obstructive respiratory disturbance index (RDI) greater than 15 events per hour, or an obstructive RDI between 5 and 14 events per hour that is accompanied by daytime sleepiness, loud snoring, witnessed breathing interruptions, or awakenings due to gasping or choking. The obstructive RDI is the number of obstructive apneas, obstructive hypopneas, and respiratory effort related arousals per hour of sleep. The report summarizes the following:

- BPAP, pressure relief, or APAP can be considered in the management of OSA in CPAP-intolerant patients (Consensus).
- BPAP is an optional therapy in some cases where high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation is present.
- Alternative therapies (eg, an oral appliance or upper airway surgery) may be offered to patients who decline positive airway pressure therapy and who have mild to moderate OSA, amenable upper airway anatomy, and a preference for such treatment. 8

American Academy of Pediatrics (AAP) 2012 guidelines for the diagnosis and management of childhood obstructive sleep apnea syndrome indicate that if a child is determined to have OSAS, has a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery, the clinician should recommend adenotonsillectomy as the first line of treatment. If the child has OSAS but does not have adenotonsillar hypertrophy, other treatment should be considered. Clinicians should refer patients for CPAP management if symptoms/signs or objective evidence of OSAS persists after adenotonsillectomy or if adenotonsillectomy is not performed. 12

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**RESOURCE REFERENCES**

3. Hayes Search & Summary Bilevel Positive Airway Pressure (BPAP) for Obstructive Sleep Apnea (OSA). Winifred Hayes Inc. Lansdale, PA. May 1, 2013


24. Advanced Medical Review (AMR): Policy reviewed by MD Board certified in Internal Medicine, Pulmonary Disease, Critical Care, Sleep Medicine. 8/29/13