Sleep Disorder Treatment with Positive Airway Pressure

MEDICAL POLICY NUMBER: 56

Effective Date: 3/1/2024

Last Review Date: 10/2023

Next Annual Review: 5/2024

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to the Oregon Administrative Rule (OAR) 410-122-0202 & 410-122-0205 and Guideline Note 27 of the Oregon Health Plan (OHP) Prioritized List of Health Services for Treatment of Sleep Apnea.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Notes:

- This medical policy does not address positive airway pressure (PAP) therapy in patients 17 years of age or younger, which may be considered medically necessary.
- Positive airway pressure (PAP) therapy would be considered a duplicative service and not covered in mild OSA if member chose oral appliance therapy.

Home Titration with Auto-Titrating Positive Airway Pressure (APAP)

I. Home titration with APAP to determine a fixed continuous positive airway pressure (CPAP) level and initiate CPAP treatment is considered **medically necessary** when **both** (A. and B.) of the following criteria are met:

   A. The patient meets **at least one** of the following (1. or 2.) criteria:
      1. The patient has been diagnosed, using polysomnography or home sleep apnea testing, with mild OSA (defined as AHI or RDI of 5 to 14 events per hour) and meets **at least one** of the following (a.-f.) criteria:
         a. Impaired cognition; **or**
         b. Mood disorders; **or**
         c. Insomnia; **or**
         d. Documented hypertension; **or**

e. Ischemic heart disease; **or**
f. History of stroke; **or**

2. The patient has been diagnosed, using polysomnography or home sleep apnea testing, with moderate or severe OSA (defined as AHI or RDI of 15 or more events per hour); **and**

B. The patient **does not have any** of the following (1.-6.) comorbid conditions that would be expected to degrade the accuracy of APAP:
1. Congestive heart failure; **or**
2. Chronic obstructive pulmonary disease; **or**
3. Prior diagnosis of central sleep apnea; **or**
4. Neuromuscular disorders (e.g., muscular dystrophy, myasthenia gravis); **or**
5. Central sleep apnea; **or**
6. Obesity hypoventilation syndrome.

II. A follow-up home titration with APAP is considered **medically necessary** when **all** of the following (A. and B.) criteria are met:

A. To determine if a pressure adjustment is needed in patients not responding to or tolerating PAP therapy or whose symptoms have returned despite an initial response to PAP therapy; **and**
B. The patient **does not have any** of the following (1.-6.) comorbid conditions that would be expected to degrade the accuracy of APAP:
1. Congestive heart failure; **or**
2. Chronic obstructive pulmonary disease; **or**
3. Prior diagnosis of central sleep apnea; **or**
4. Neuromuscular disorders (e.g., muscular dystrophy, myasthenia gravis); **or**
5. Central sleep apnea; **or**
6. Obesity hypoventilation syndrome.

III. Home titration with APAP is considered **not medically necessary** when criteria I. or II. above is not met.

Initial Trial (90 days) of Continuous Positive Airway Pressure (CPAP)/Auto-Titrating Positive Airway Pressure (APAP)

IV. The initial trial (90 days) of CPAP or APAP may be considered **medically necessary** for the treatment of obstructive sleep apnea (OSA) when **at least one** of the following (A. or B.) criteria are met:

A. The patient has been diagnosed, using polysomnography or home sleep testing, with mild OSA (defined as AHI or RDI of 5 to 14 events per hour) and meets **at least one** of the following (1.-6.) criteria:
1. Impaired cognition; **or**
2. Mood disorders; **or**
3. Insomnia; **or**
4. Documented hypertension; **or**
5. Ischemic heart disease; **or**

6. History of stroke; **or**

B. The patient has been diagnosed, using polysomnography or home sleep testing, with moderate or severe OSA (defined as AHI or RDI of 15 or more events per hour).

V. The initial trial (90 days) of CPAP or APAP is considered **not medically necessary** when criterion IV. above is not met.

Initial Trial (90 days) of Bilevel Positive Airway Pressure (BiPAP)

BiPAP without Back-Up Rate Feature

VI. The initial trial (90 days) of BiPAP without a back-up rate feature may be considered **medically necessary** in patients diagnosed with obstructive sleep apnea who are intolerant to CPAP/APAP therapy or CPAP/APAP therapy is ineffective (failure of symptom resolution despite optimal therapy) when **all** of the following (A.-E.) criteria are met:

A. The patient meets criterion IV. above; **and**
B. The CPAP/APAP device has been properly fitted; **and**
C. The patient is using the CPAP/APAP device correctly; **and**
D. The patient was unable to tolerate the titrated pressure level; **and**
E. Lower pressure levels were attempted but failed due to **at least one** of the following (1.-3.):
   1. Obstructive sleep apnea (OSA) symptoms were not adequately controlled; **or**
   2. AHI or RDI levels were not reduced to acceptable levels; **or**
   3. Sleep quality was not improved.

VII. The initial trial (90 days) of BiPAP without a back-up rate feature may be considered **medically necessary** in patients with an established diagnosis of central sleep apnea who meet **all** of the following (A. and B.) criteria:

A. Obstructive sleep apnea has been excluded or treated; **and**
B. A titration study (split- or whole-night) demonstrated significant improvement of sleep-related hypoventilation adjusted to the settings that will be prescribed for home use.

BiPAP with Back-Up Rate Feature

VIII. The initial trial (90 days) of BiPAP with a back-up rate feature may be considered **medically necessary** in patients with an established diagnosis of central sleep apnea who meet **all** of the following (A.-C.) criteria:

A. Obstructive sleep apnea has been excluded or treated; **and**
B. BiPAP without back-up rate feature was attempted but not successful due to **either** of the following (1. or 2.):
   1. Oxygen saturation level is 88% or less for at least 5 minutes while the patient breathes their usual FiO2; **or**
   2. The patient demonstrates Cheyne Stokes respiration for 5 continuous minutes with oxygen saturation falling to less than 88% at least once during that 4-minute interval; **and**

C. A titration study (split- or whole-night) demonstrated significant improvement of sleep-related hypoventilation adjusted to the settings that will be prescribed for home use.

IX. The initial trial (90 days) of Adaptive Servo-Ventilation (ASV) devices (see Policy Guidelines) may be considered **medically necessary** for patients with central sleep apnea when both of the following criteria are met (A.-B.):
   A. Criterion VIII. above is met; **and**
   B. One of the following criteria is met (1-2):
      1. Patient does not have congestive heart failure or has an ejection fraction of at least 45%; **or**
      2. Patient has mild congestive heart failure-related central sleep apnea.

X. The initial trial (90 days) of Adaptive Servo-Ventilation (ASV) devices are considered **not medically necessary** when criterion IX. above is not met.

BiPAP with or without Back-Up Rate Feature

XI. The initial trial (90 days) of BiPAP/BiPAP AVAPS with or without the back-up rate feature may be considered **medically necessary** in the management of patients with severe chronic obstructive pulmonary disease (COPD) who meet **at least one** of the following (A. or B.) criteria:

   A. PaCO2 measured by arterial blood gas drawn while the patient is awake and breathing their usual FiO2 is 45 mmHg or greater; **or**
   B. Sleep oximetry demonstrates oxygen saturation of 88% or less for at least 5 continuous minutes while the patient breathes oxygen at 2L per minute or their usual FiO2 (whichever is higher).

XII. The initial trial (90 days) of BiPAP/BiPAP AVAPS with or without the back-up rate feature may be considered **medically necessary** in the management of patients with certain restrictive thoracic disorders when **all** of the following (A. and B.) criteria are met:

   A. The patient has an established diagnosis of a progressive neuromuscular disease or a severe thoracic cage abnormality; **and**
   B. The patient meets at least one of the following criteria:
      1. PaCO2 measured by arterial blood gas drawn while the patient is awake and breathing their usual FiO2 is 45 mmHg or greater; **or**
      2. Sleep oximetry demonstrates oxygen saturation of 88% or less for at least five continuous minutes while the patient breathes their usual FiO2; **or**
      3. For patients with neuromuscular disease only, maximal inspiratory pressure is less than 60 cm H2O or forced vital capacity is less than 50% predicted.

XIII. The initial trial (90 days) of BiPAP/BiPAP AVAPS is considered **not medically necessary** when **at least one** of the criteria (VI.-XII.) above is not met.

Treatment with PAP Therapy Beyond 90 Days

XIV. Ongoing treatment (beyond 90 days) with PAP therapy (CPAP, APAP, BiPAP/BiPAP AVAPS, or Adaptive Servo-Ventilation devices) may be considered **medically necessary** when any of the following criteria (A. – C.) are met:

A. Objective evidence demonstrates patient compliance with therapy during the initial trial. Compliance is defined as use of the PAP device for ≥ 4 hours per night on 70% of nights during a consecutive 30-day period within the preceding 90 days of receipt of the device; **or**
B. Request is for a 60-day trial extension and documents indicate either of the following:
    1. A significant attempt to meet patient compliance criteria is documented (e.g., multiple mask fittings); **or**
    2. Documents show there were extenuating circumstances which precluded meeting compliance (e.g., respiratory disorder, hospital admission)**; or**
C. A PAP therapy re-trial is requested and all of the following criteria (1. – 4.) are met:
    1. Initial 90-day trial and 60-day trial extension failed; **and**
    2. Face-to-face clinical re-evaluation has been performed by the treating physician to determine the etiology of the failure to respond to PAP therapy
    3. A new treatment plan has been established; **and**
    4. Applicable criteria above for the initial trial are met.

XV. Ongoing treatment with PAP therapy is considered **not medically necessary** when criterion XIV. above is not met.

Replacement of PAP Equipment

XVI. Replacement of PAP equipment may be considered **medically necessary** when it has reached the end of its five-year reasonable use lifetime (RUL) or when wear and tear renders the item non-functioning and non-repairable.

XVII. Replacement of PAP equipment is considered **not medically necessary** when criterion XIV., above, is not met.

Dual PAP with Oral Appliance Therapy

XVIII. Dual PAP with oral appliance therapy is considered **not medically necessary**, including but not limited to, as a convenience item (e.g. travel).

Other PAP Therapies

XIX. Other PAP therapies not discussed above are considered **not medically necessary**, including but not limited to the ULTepap™ System.

Upper Airway Resistance Syndrome (UARS)

XX. Positive airway pressure for the treatment of upper airway resistance syndrome is considered **not medically necessary**.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Sleep Disorder Testing, MP60
- Sleep Disorder Treatment: Surgical, MP179
- Sleep Disorder Treatment with Oral and Sleep Position Appliances, MP 46

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DEFINITIONS

- **Apnea**: the cessation of airflow for at least 10 seconds
- **Hypopnea:** abnormally slow or shallow breathing resulting in reduced airflow
- **Apnea-hypopnea index (AHI):** the number of apnea and hypopnea events per hour of sleep; used to indicate the severity of sleep apnea
- **Respiratory disturbance index (RDI):** the number of apnea and hypopnea events per hour of sleep plus the number of respiratory-effort related arousals (RERAs) per hour of sleep
- **Respiratory-effort related arousals (RERAs):** an abnormal breathing event which does not meet the criteria for an apnea of hypopnea, but is an arousal of sleep associated with a respiratory event noted during a sleep study
- **Mild sleep apnea**: AHI or RDI score of 5 to 14 and is typically associated with involuntary daytime sleepiness during activities that require little attention such as reading or watching television.
- **Moderate sleep apnea**: AHI or RDI score of 15 to 30 associated with involuntary sleepiness during activities that require moderate attention such as meetings or presentations.
- **Severe sleep apnea**: AHI or RDI score of greater than 30 and is typified by daytime sleepiness during activities that require active attention such as driving or talking. The score may exceed 100 in patients with very severe OSA.
- **Upper airway resistance syndrome (UARS):** AHI less than 5, not meeting OSA criteria but still experiencing daytime sleepiness due to partial collapse of the airway and increased resistance to airflow.

BACKGROUND

Sleep Disorders

Obstructive Sleep Apnea (OSA)

OSA is a sleep disorder in which a person stops breathing during sleep due to an obstruction of the upper airway. This obstruction is due to inadequate motor tone of the tongue or airway dilator muscles. Signs and symptoms of OSA include witnessed apneas, snoring, daytime sleepiness, obesity, and large

neck circumference. OSA has become increasingly recognized as an independent risk factor for cardiac, neurologic, and perioperative morbidities.

Central Sleep Apnea (CSA)

In contrast to OSA where ongoing respiratory efforts are observed, CSA is defined by a lack of respiratory effort during the cessation of airflow. This results in insufficient or absent ventilation and compromised gas exchange during sleep. CSA is associated with frequent nighttime awakenings, excessive daytime sleepiness, and increased risk for adverse cardiovascular outcomes. There are several manifestations of CSA, including idiopathic CSA (CSA of unclear etiology), narcotic-induced central apnea, high altitude periodic breathing, and Cheyne-Stokes breathing (breathing pattern characterized by changes in tidal volume and apneas).

Obesity Hypoventilation Syndrome (OHS)

OHS is a type of CSA that is typically defined as a combination of obesity (body mass index > 30 kg/m2) and arterial hypercapnia (Paco2 >45 mm Hg) during wakefulness not explained by other known causes of hypoventilation. Symptoms may be similar to those of OSA, including morning headaches and excessive daytime sleepiness.

Positive Airway Pressure (PAP)

According to the American Sleep Apnea Association, "(p)ositive airway pressure, or PAP, is the most effective and most widely used method for treating obstructive sleep apnea, particularly in its severe form—25 or more apneas and hypopneas per hour."[1] A PAP machine consists of (1) the machine itself (2) a nasal, oral, or oronasal facial mask that is secured to the face with head gear and (3) a flexible hose that connects the mask and the machine. PAP works by blowing pressurized air through the airway at a pressure high enough to keep the throat open; thus counteracting the effects of obstructive sleep apnea. The pressure level is determined using a titration study. Titration determines a high enough pressure to ensure the airway is completely open without disturbing sleep. There are three different PAP delivery methods:

1. Continuous Positive Airway Pressure (CPAP): continuous fixed pressure during the entire sleep period
2. Auto Titrating Positive Airway Pressure (APAP): varies the pressure delivered depending on changes in airflow resistance
3. Bilevel Positive Airway Pressure (BiPAP): delivers airflow at different rates during the inspiration (inhalation) versus expiration (exhalation) phases of breathing
    a. Some BiPAP machines also have a back-up rate feature, which ensures the patient receives a minimum number of breaths per minute.

Adaptive Servo-Ventilation (ASV)

ASV is a form of bilevel positive airway pressure (BiPAP) therapy used to treat sleep-related breathing disorders, including central sleep apnea. ASV uses both inspiratory and expiratory pressure. ASV therapy differs from CPAP or BiPAP in use of an automatic device that stabilizes breathing by performing breath

to breath analysis and adjustment of settings accordingly. Depending on breathing effort, the device will automatically adjust the amount of airflow it delivers to maintain a steady minute ventilation.[2]

Upper Airway Resistance Syndrome

Upper airway resistance syndrome is a sleep disorder characterized by increased resistance to airflow in the upper airway during sleep. While it shares some similarities to OSA, UARS does not involve complete blockage of the airway. Instead, individuals with UARS experience partial obstruction or resistance, leading to disruptions in their sleeps. Common symptoms include excessive daytime sleepiness, frequent awakenings during the night, snoring, fatigue, morning headaches, difficulty concentrating.[3]

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Continuous Positive Airway Pressure Devices

Several continuous positive airway pressure devices have received FDA approval under the 510(k) premarket notification process. These devices are classified as class II under the product code "BZD". Additional information is available by searching the FDA 510(k) database for product code BZD.

Auto Titrating Positive Airway Pressure Devices

Several auto titrating positive airway pressure devices have received FDA approval under the 510(k) premarket notification process. These devices are classified as class II under the product code "BTT". Additional information is available by searching the FDA 510(k) database for product code BTT.

Bilevel Positive Airway Pressure Devices

Several bilevel positive airway pressure (BiPAP) devices have been approved under the FDA 510(k) premarket notification process. These devices are classified as class II under the product code "BZD". Additional information is available by searching the FDA 510(k) database for product code BZD.

Device Name & Manufacturer	Indications for Use
BiPAP Pro (Respironics Inc.)[4]	For the treatment of obstructive sleep apnea only for use in the home or hospital/institution environment in adult patients.
BiPAP S/T-D 30 (Respironics Inc.)[5]	For hospital or institutional use for treatment of obstructive sleep apnea, respiratory failure, or respiratory insufficiency.

BiPAP Auto (Respironics Inc.)[6]	The BiPAP Auto-system delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea. The device is for use in the home or hospital/institutional environment on adult patients.
Hoffrichter Vector Bi (Hoffrichter GmbH)[7]	For treatment of obstructive sleep apnea (OSA) in adult patients weighing at least 30 kg. These devices are not intended for use with ventilator-dependent patients.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP), and auto titrating positive airway pressure (APAP) for the treatment of sleep related disorders. Below is a summary of the available evidence identified through March 2023. Due to the abundance of applicable literature, the evidence search was limited to systematic reviews and U.S. evidence-based clinical practice guidelines.

Positive Airway Pressure: Continuous (CPAP), Autotitrating (APAP), and Bilevel (BiPAP)

In 2011, the Agency for Healthcare Research and Quality conducted a systematic review of the evidence to evaluate the diagnosis and treatment of obstructive sleep apnea (OSA) in adults.[8] Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. The key questions focused on OSA screening and diagnosis, treatments, associations between apnea-hypopnea index (AHI) and clinical outcomes, and predictors of treatment compliance. In regards to positive airway pressure therapy, the authors evaluated the following:

- CPAP versus control
- CPAP versus sham CPAP
- Oral versus nasal CPAP
- APAP versus fixed CPAP
- BiPAP versus fixed CPAP
- Flexible BiPAP versus fixed CPAP
- C-Flex™ versus fixed CPAP
- Humidification in CPAP.

<u>CPAP versus Control</u>

The authors identified 11 quality B and 11 quality C trials evaluating CPAP versus control. “The studies reviewed generally found that CPAP was superior in reducing AHI, improving ESS, reducing arousal index, and raising the minimum oxygen saturation.”[8] Although heterogeneous, meta-analysis confirmed these results. Most studies found no significant difference in quality of life or neurocognitive measures. The authors concluded that the reviewed studies provide sufficient evidence supporting large improvements in sleep measures with CPAP compared to control. Additionally, the authors stated that, “given the large magnitude of effect on the intermediate outcomes of AHI and ESS, the strength of evidence that CPAP is an effective treatment to alleviate sleep apnea signs and symptoms was rated moderate.”[8]

CPAP versus Sham CPAP

A total of 5 quality A, 13 quality B, and 6 quality C trials were included in the evaluation of CPAP versus sham CPAP. Of these trials, 16 compared APAP with sham and 8 trials compared CPAP with sham. The results of the studies indicate CPAP is superior in reducing AHI, improving ESS, and reducing arousal index. Additionally, these findings were confirmed through meta-analysis. Most studies found no significant differences in regards to quality of life and neurocognitive function. In regards to the effects of CPAP on blood pressure, "about half of the studies reported significant blood pressure reduction, favoring CPAP, and the other half reported no significant differences."[8] Ultimately, the authors concluded a sufficient and moderate body of evidence to support large improvements in sleep measures with CPAP versus sham.

Oral versus Nasal CPAP

The authors identified 3 small trails with inconsistent results; therefore, the overall evidence was insufficient to provide any substantive conclusions regarding the efficacy of oral versus nasal CPAP.

APAP versus Fixed CPAP

The authors identified 21 trials (mostly quality B or C) comprised of over 800 patients evaluating APAP versus fixed CPAP. The results of these studies indicate that APAP reduces sleepiness as measured by ESS (Epworth Sleepiness Scale) by approximately 0.5 points more than fixed CPAP. "The two devices were found to result in clinically similar levels of compliance (hours used per night) and changes in AHI from baseline, quality of life, and most other sleep study measures."[8] CPAP was found to improve minimum oxygen saturation more than APAP; however, only by about 1%. There was limited evidence regarding the effects of CPAP or APAP on blood pressure. Regarding APAP versus fixed CPAP, the authors concluded "despite no or weak evidence on clinical outcomes, overall the strength of evidence is moderate that autoCPAP and fixed CPAP result in similar compliance and treatment effects for patients with OSA."[8]

BiPAP versus Fixed CPAP

A total of 5 small trials (mostly quality C) were identified for the evaluation of BiPAP versus fixed CPAP. The studies had, "largely null findings did not support any substantive differences in the efficacy of bilevel CPAP versus CPAP in the treatment of patients with OSA."[8] The authors concluded insufficient evidence regarding BiPAP versus CPAP due to the clinical heterogeneity, imprecision, and null results of included studies.

Flexible BiPAP versus Fixed CPAP

The authors found insufficient evidence (only a single study) to evaluate flexible BiPAP versus fixed CPAP.

C-Flex™ versus Fixed CPAP

The authors included 4 trials of B and C quality to evaluate C-Flex versus fixed CPAP. The trials had mostly null results and did not support and significant difference in the efficacy of C-Flex versus fixed CPAP in improving compliance.

Humidification in CPAP

A total of 5 trials examined different aspects of humidification with positive airway pressure. Some studies reported a benefit of humidification in improving patient compliance; however, this was not consistent across all studies. The authors concluded "the strength of evidence is insufficient to determine whether there is a difference in compliance or other outcomes between positive airway pressure treatment with and without humidification."[8]
This AHRQ systematic review was of very good quality and had several strengths, including:

1. the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers
2. contacting authors of selected studies for additional information or data
3. assessment of heterogeneity and publication bias
4. meta-analyses only being conducted when studies were determined to be homogeneous with respect to population, treatment, and outcome measures
5. sensitivity analyses to evaluate the influence of studies with a high risk of bias or high losses to follow-up

Limitations of this systematic review are seen in the inclusion of studies with a high risk of bias, significant inter-study heterogeneity, and the potential for publication bias due to a small number of studies included in some meta-analyses. Regarding the use of PAP, the authors concluded that "CPAP is highly effective in minimizing AHI and improving sleepiness."[8]

Auto Titrating Positive Airway Pressure (APAP)

In 2019, Kennedy and colleagues published a Cochrane database systematic review of studies that compared automatically adjusting CPAP (auto-CPAP), bilevel positive airway pressure (bi-PAP), CPAP with expiratory pressure relief (CPAPexp), heated humidification plus fixed CPAP, automatically adjusting CPAP with expiratory pressure relief, Bi-PAP with expiratory pressure relief, auto bi-PAP and CPAPexp with wakefulness detection with fixed pressure setting.[9] The primary focus was comparing APAP to fixed CPAP, which the authors based on 36 studies with 2,135 participants. In pooled analysis, the authors found that most studies recruited participants who were recently diagnosed with OSA and had not used CPAP previously (participants had excessive sleepiness [ESS: 13], severe sleep disturbance [AHI ranged from 22 to 59], and average body mass index [BMI] of 35 kg/m2). Equipment was used in the home setting and most studies reported outcomes of 12 weeks or less. The authors concluded that auto-CPAP probably increases machine usage by about 13 minutes per night in adults with moderate to severe sleep apnoea starting positive airway pressure therapy. Somewhat validating the authors in the next review summary, they did not find the effect on daytime sleepiness scores with auto-CPAP to be clinically meaningful. They stated that the use of validated quality of life studies has been limited to-date, though where implemented, the effect sizes have not exceeded proposed clinically important differences; and that an established standardized approach to measuring tolerability would aid in evaluating benefits with harms.

In 2012, Ip et al. published a systematic review and meta-analysis to evaluate auto titrating (APAP) versus fixed continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea (OSA).[10] Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. Study authors were also contacted, if necessary, for additional information or data. The outcomes of interest included objective clinical outcomes (e.g., cardiovascular events, hypertension), sleep and wakefulness related clinical outcomes (e.g., quality of life, sleepiness measures, neurocognitive tests), sleep study measures (e.g., AHI), comorbidity intermediate outcomes (e.g., blood pressure), compliance, and adverse events.

Following systematic review, the authors identified 24 randomized controlled trails comparing APAP with fixed CPAP treatment in patients with OSA. No trials were identified that evaluated clinical outcomes. All included trials evaluated compliance. No statistically significant differences were observed in device usage in 20 trials, while 4 trials reported a significant usage increase in APAP. Meta-analysis showed a statistically significant difference between APAP and CPAP in favor of APAP (p=0.006). In regards to AHI, "none of the studies reported a statistically significant difference in AHI (events/hour) between APAP and CPAP."[10] Additionally, meta-analysis indicated a non-significant difference between APAP and CPAP in regards to AHI. Meta-analysis of the Epworth sleepiness scale yielded a statistically significant difference between APAP and CPAP in favor of APAP (p=0.005). "Fixed CPAP improved minimum oxygen saturation by 1.3% more than APAP (95% CI, 0.4 to 2.2%)."[10]

This systematic review was of good quality and had several methodological strengths, including:
1. the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers
2. contacting authors of selected studies for additional information or data
3. assessment of heterogeneity and publication bias
4. sensitivity analyses to evaluate the influence of studies with a high risk of bias or high losses to follow-up

Limitations are present in the significant amount of inter-study heterogeneity and possible publication bias due to a small number of studies being included in some meta-analyses. Ultimately, the authors concluded "(s)tatistically significant differences were found but clinical importance is unclear. Because the treatment effects are similar between APAP and CPAP, the therapy of choice may depend on other factors such as patient preference, specific reasons for non-compliance and cost."[10]

Bilevel Positive Airway Pressure (BiPAP)

In 2013 (updated 2017; archived 2018), Hayes conducted an evidence review to evaluate bilevel positive airway pressure (BiPAP) for the treatment of obstructive sleep apnea (OSA) in adults.[11] The review included 9 studies (3 randomized controlled trials, 1 randomized within-subject crossover comparison, 5 nonrandomized studies) of poor to good quality evaluating the efficacy of BiPAP to improve symptoms of OSA. The included studies encompassed 392 patients, with individual sample sizes ranging from 11 to 130. The outcomes of interest were generally measured using polysomnography and included several sleep and respiratory parameters (e.g., AHI, RDI, total sleep time, REM sleep time, and oxygen saturation/desaturation). In addition, daytime sleepiness was commonly measured using the Epworth Sleepiness scale (ESS).

The findings from all studies suggest BiPAP therapy significantly decreases AHI from pretreatment levels. Additionally, the results from comparative studies indicate BiPAP does not differ from CPAP in the improvement of AHI. "Findings from the 5 available studies indicate that BiPAP therapy improves daytime sleepiness on the ESS relative to pretreatment, and results from comparative studies show that the efficacy of BiPAP to improve ESS scores does not differ from other forms of positive air pressure (PAP) therapy, including CPAP and APAP."[11] In regards to oxygen saturation, findings from all studies evaluating this variable indicated that BiPAP significantly improves oxygen saturation. Furthermore, studies comparing BiPAP with CPAP or APAP indicate BiPAP does not differ from CPAP/APAP in terms of oxygen saturation. The results of the evidence review also indicate compliance with BiPAP therapy is similar to that of CPAP. A total of 5 studies evaluated BiPAP in patients who failed CPAP treatment and showed improvements in BiPAP usage.

Hayes determined the overall quality of evidence to be low due to "lack of power analysis to determine appropriate sample size, heterogeneity in type of bilevel positive airway pressure (BiPAP) device evaluated, enrollment of individuals with medical conditions (i.e., comorbid heart disease) or sleep apnea syndromes other than obstructive sleep apnea (OSA) that could confound results, and short duration of treatment with BiPAP."[11] Ultimately, Hayes concluded the following ratings for BiPAP in the treatment of OSA in adults:

- B (some proven benefit): For bilevel positive airway pressure (BiPAP) treatment in adults with obstructive sleep apnea (OSA). This Rating reflects the significant improvement in sleep-disordered breathing, subjective daytime sleepiness, and oxygen saturation that are comparable in magnitude to those observed with continuous positive airway pressure (CPAP), the standard of care for OSA.
- D2 (insufficient evidence): For BiPAP treatment in adults with OSA and comorbid illnesses, such as reduced respiratory function or obesity, or in those with OSA and a comorbid sleep disorder. This Rating reflects the paucity of evidence regarding the efficacy and safety of BiPAP in these patient populations.

Dual PAP with Oral Appliance Therapy

Several non-randomized studies were identified evaluating the safety and efficacy of combined PAP and oral appliance therapy. While results showed improvements in patients' symptoms and quality of life, studies were limited by extremely small sample sizes (n=7-10) and limited follow-up.[12-14]

Upper Airway Resistance Syndrome (UARS)

In 2015, Godoy and colleagues published results of a systematic review of treatments for UARS in adults. The review included 7 case reports, 8 nonrandomized studies, and 2 RCTs. Studies had significant heterogeneity in terms of definition of UARS and treatment. The authors concluded that there are few well designed studies available for UARS treatment. "CPAP has been the primary therapy prescribed, but its effectiveness has been limited because of low patient compliance and there are no randomized controlled trials evaluating this type of treatment in UARS patients. The available studies that have evaluated surgical treatments of UARS patients have methodological limitations and low numbers of patients evaluated. Oral appliances seem to be an effective option, but only case reports and small case series have been reported, and the efficacy of these devices is not yet established for this group of patients. Randomized controlled trials comparing different modalities of treatment with larger numbers

of patients and including long-term follow-up are important to better define and establish treatment options in UARS patients."[15]

CLINICAL PRACTICE GUIDELINES

American Academy of Sleep Medicine (AASM)

In 2019, the AASM published an evidence-based clincial practice guideline evaluating the safety andefficacy of positive airway pressure for the treatment of obstructive sleep apnea.[16] A "strong" recommendation is one that clinicans should follow under most circumstances. A "conditional" recommendation refelects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patient. Investigators issued the following recommendations:

- We recommend that clincians use PAP, comared to no tehrapy, to treat OSA in adults with excessive sleepiness (Strong)
- We suggest that clinicans use PAP, compared to no therapy, to treat OSA in adults with impaired sleep-related quality of life (Conditional)
- We uggest that clincians use PAP, compared to no theray, to treat OSA in adults with comorbid hypertension (Conditional)
- We recommend that PAP therapy be initiated using either APAP at home or in-laboratory PAP titration in adults with OSA and no significant comorbidities (Strong)
- We recommend that clinicans use either CPAP or APAP for ongoing treatnment of OSA in adults (Strong)
- We suggest that clinicans use CPAP or APAP over BPAP in the routine treatment of OSA in adults (Conditional)
- We recommend that educational interventions be given with initiation of PAP therapy in adults with OSA (Strong)
- We suggest that behavioral or troublehsooting interventions be given during the initial period of PAP therapy in adults with OSA (conditional).[16]

In 2016, the AASM updated their recommendation addressing Adaptive Servo-Ventilation (ASV) for the treatment of central sleep apnea syndrome related to congestive heart failure.[17] Authors recommended ASV as an option to normalize the treatment of central sleep apnea related to congestive heart failure in adults with an ejection fraction > 45% or mild congestive heart failure-related central sleep apnea.

Carelon

In 2023, Carelon issued clinical appropriateness guidelines for sleep disorder management, including appropriate use criteria for diagnostic and treatment management of obstructive sleep apnea using APAP or CPAP.[18]

Treatment with CPAP is appropriate for a patient aged 19 years or older when conditions A and B below are met:

A. Home or lab based sleep study demonstrates one of the following (1–2)
    1. AHI greater than or equal to 15
    2. AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition,

mood disorders, insomnia, treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications), ischemic heart disease, history of stroke. AND

B. Appropriate CPAP level has been determined from one of the following (1–5)
    1. Split-night sleep study
    2. Whole-night lab based titration study following a study where the CPAP level was not determined during the therapeutic portion or the patient has OSA but did not meet criteria for PAP titration during the study
    3. Whole-night lab based titration study in a patient in whom APAP is contraindicated (e.g., congestive heart failure [CHF], chronic obstructive pulmonary disease [COPD], obesity hypoventilation syndrome or central sleep apnea [defined as having at least 50% central events or more than five (5) central events per hour])
    4. APAP titration trial
    5. Whole-night lab based titration study when home, unmonitored APAP titration was unsuccessful

Treatment with APAP is appropriate when a patient meets conditions A and B below

A. Home or lab based sleep study demonstrates one of the following (1–2)
    1. AHI greater than or equal to 15
    2. AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications), ischemic heart disease, history of stroke. AND
B. The patient has none of the following contraindications (1–6) to the use of APAP
    1. Age 18 years or younger
    2. CHF
    3. COPD
    4. Central sleep apnea (defined as having at least 50% central events or more than five [5] central events per hour)
    5. Neuromuscular disorders (e.g. muscular dystrophy, myasthenia gravis)
    6. Obesity hypoventilation syndrome defined as a body mass index (BMI) >30 kg/m2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology or medications. Documentation of hypoventilation requires either an increase in arterial PCO2 (or surrogate measure) to >55 mmHg for at least 10 minutes or a >10 mmHg increase in arterial PCO2 (or surrogate measure) during sleep (compared to an awake supine value) to a value EXCEEDING 50 mmHg for at least 10 minutes.

Ongoing treatment is indicated for patients who demonstrate compliance with therapy.

Demonstration of compliance is required every 90 days for the first year of therapy and annually thereafter. Compliance is defined as:

1. Use of the CPAP device for greater than or equal to four (4) hours per night on 70% of nights during a consecutive thirty (30) day period within the preceding 90 days; OR
2. There is clinical evidence submitted by the treating provider that demonstrates continued clinical benefit from use of the positive airway pressure device.

BiPAP (without back-up rate feature) is appropriate for patients with OSA who have failed CPAP/APAP or require supplemental ventilatory support due to a hypoventilation syndrome

BiPAP is appropriate for patients with established CSA diagnosed by an in-lab sleep study when both of the following (a and b) apply:

a. OSA has been excluded or treated
b. A titration study (split-night or whole-night) has demonstrated significant improvement of sleep-related hypoventilation adjusted to the settings that will be prescribed for home use (while breathing the individual's usual FiO2)

BiPAP (with back-up rate feature) is appropriate for patients with established CSA diagnosed by an in-lab sleep study and all of the following (a–c) apply:

a. OSA has been excluded or treated
b. BiPAP without back-up rate had been attempted but has not successfully treated episodes of desaturation as evidenced by either of the following:
    1. Oxygen saturation level is 88% or less for at least five (5) minutes while the patient breathes his/her usual FiO2; OR
    2. The patient demonstrates Cheyne Stokes respiration for five (5) continuous minutes with oxygen saturation falling to less than 88% at least once during that 5-minute interval
c. A titration study (split-night or whole-night) has demonstrated significant improvement of sleep-related hypoventilation adjusted to the settings that will be prescribed for home use (while breathing the individual's usual FiO2)

BiPAP (with or without back-up rate feature) is appropriate in the management of patients with severe COPD demonstrating either of the following (a or b):

a. PaCO2 measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FiO2 is 45 mmHg or greater; OR
b. Sleep oximetry demonstrates oxygen saturation of 88% or less for at least five continuous minutes while the patient breathes oxygen at 2L per minute or his/her usual FiO2 (whichever is higher)

BiPAP (with or without back-up rate feature) is appropriate in the management of patients with certain restrictive thoracic disorders when both a and b below are true

a. The patient has an established diagnosis of a progressive neuromuscular disease, e.g., amyotrophic lateral sclerosis (ALS) OR a severe thoracic cage abnormality; AND
b. One of the following statements is true:
    1. PaCO2 measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FiO2 is 45 mmHg or greater.
    2. Sleep oximetry demonstrates oxygen saturation of 88% or less for at least five continuous minutes while the patient breathes his/her usual FiO2
    3. Maximal inspiratory pressure is less than 60 cm H2O or forced vital capacity is less than 50% of predicted (applies to patients with progressive neuromuscular disease only)

Ongoing treatment with BiPAP is indicated for patients who demonstrate compliance with therapy. Demonstration of compliance is required every 90 days for the first year of treatment and annually thereafter. Compliance is defined as:

1. Use of the BiPAP device for greater than or equal to four (4) hours per night on 70% of nights during a consecutive thirty (30) day period within the preceding 90 days; OR
2. There is clinical evidence submitted by the treating provider that demonstrates continued clinical benefit from use of the positive airway pressure device.

American College of Physicians (ACP)

The 2013 ACP evidence-based guideline for the management of obstructive sleep apnea in adults recommended the following:[19]

> "ACP recommends continuous positive airway pressure (CPAP) treatment as initial therapy for patients diagnosed with OSA. (Grade: strong recommendation; moderate-quality evidence). In patients with excessive daytime sleepiness who have been diagnosed with OSA, CPAP is the most extensively studied therapy. This treatment has been shown to improve Epworth Sleepiness Scale (ESS) scores, reduce AHI and arousal index scores, and increase oxygen saturation. However, CPAP has not been shown to increase quality of life. Evidence on the effect of CPAP on cardiovascular disease, hypertension, and type 2 diabetes was insufficient. Studies have evaluated various alternative CPAP modifications. Fixed and auto-CPAP, as well as C-Flex, have similar adherence and efficacy. Data were insufficient to determine the comparative efficacy of other CPAP modifications. Greater AHI and ESS scores were generally associated with better adherence to CPAP."

American Society of Anesthesiologists (ASA)

The 2006 (revised 2014) ASA evidence-based guidelines for the perioperative management of patients with obstructive sleep apnea gave the following recommendations regarding positive airway pressure therapy:[20]

> "Preoperative initiation of continuous positive airway pressure (CPAP) should be considered, particularly if OSA is severe. For patients who do not respond adequately to CPAP, noninvasive positive pressure ventilation should be considered."

National Institute for Health and Care Excellence (NICE)

In 2008 (updated 2021), NICE published evidence-based guideline for continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea/hypopnea syndrome recommended CPAP "as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAHS)."[21] Additionally, NICE recommended CPAP as a treatment option for adults with mild OSAHS if, "they have symptoms that affect their quality of life and ability to go about their daily activities, and lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate."

Oregon Health Authority Health Evidence Review Commission (HERC)

The 2014 HERC coverage guidance for the treatment of sleep apnea in adults recommended the following regarding continuous positive airway pressure:[22]

CPAP is recommended for coverage initially when all of the following conditions are met:

- 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) calculated using the CMS definition of hypopnic episode of >4% oxygen desaturation or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour; or if between 5 and 14 events with additional symptoms (weak recommendations) including one or more of the following:

        - excessive daytime sleepiness (Epworth Sleepiness Scale score > 10), or daytime sleepiness interfering with ADLs that is not attributable to another modifiable sedating condition (e.g. narcotic dependence),or
        - documented hypertension, or
        - ischemic heart disease, or
        - history of stroke;
    - Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and
    - Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

CPAP coverage subsequent to the initial 12 weeks should be based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30 day period.

UpToDate

UpToDate published a 2023 guideline on Clinical Presentation and Diagnosis of Obstructive Sleep Apnea in Adults. They state that there is currently no consensus about the optimal detection, proper management, an degree of clinical impact for UARS.[3]

EVIDENCE SUMMARY

Continuous Positive Airway Pressure (CPAP) and Auto-titrating Positive Airway Pressure (APAP) Therapy

There is enough research to show that the use of continuous positive airway pressure (CPAP) and auto titrating positive airway pressure (APAP) therapy in adults improves overall health outcomes for select populations of those with obstructive sleep apnea. In those who meet policy criteria, studies show that CPAP and APAP treatments significantly improve sleep measures, including the Apnea Hypopnea Index and Epworth Sleepiness Scale. Additionally, numerous evidence-based clinical practice guidelines recommend the use of CPAP and APAP for the treatment of obstructive sleep apnea. Therefore, the use of CPAP or APAP may be considered medically necessary for the treatment of obstructive sleep apnea in patients meeting policy criteria. There is sufficient evidence to show that the use of CPAP and APAP therapy in those who do not meet policy criteria is considered not medically necessary and is not covered.

Bilevel Positive Airway Pressure (BiPAP) Therapy

There is enough research to show that the use of bilevel positive airway pressure (BiPAP) therapy improves overall health outcomes in adults with obstructive sleep apnea (OSA) who are intolerant to CPAP/APAP or in whom CPAP/APAP was ineffective. Additionally, several evidence-based clinical practice guidelines recommend BiPAP as an effective treatment for adult OSA. The Carelon guideline as well as the American Academy of Sleep Medicine also recommends BiPAP therapy in patients with other disorders affecting sleep-related breathing; including central sleep apnea, severe chronic obstructive pulmonary disease, and restrictive thoracic disorders. Therefore, BiPAP therapy may be considered medically necessary when policy criteria are met. There is sufficient evidence to show that the use of

BiPAP therapy in those who do not meet policy criteria is considered not medically necessary and is not covered.

Dual Positive Airway Pressure with Oral Appliance Therapy

There is enough evidence to show that dual positive airway pressure (PAP) with oral appliance therapy does not improve overall health outcomes versus therapy with either PAP or a medically necessary oral appliance for those with sleep disorders, whether used for as dual therapy or for travel (e.g., as a convenience item). No clinical practice guidelines based on research were identified specifically recommending dual PAP with oral appliance therapy. Therefore, dual PAP with oral appliance therapy is considered not medically necessary and is not covered.

Upper Airway Resistance Syndrome

There is no consensus about the optimal detection, proper measurement, or degree of clinical impact of UARS and its treatment. Neither the American Sleep Disorders Association nor any other professional medical organization has issued guidelines for the diagnosis and treatment of UARS. There is also not enough high-quality research on UARS and treatment of any type, including oral appliances and CPAP. Therefore, treatment of UARS with oral and sleep position appliances is considered not medically necessary.

BILLING GUIDELINES AND CODING

HCPCS code E0601 may be used to bill for auto titrating positive airway pressure (APAP).

CODES*		
CPT	None	
HCPCS	A7049	Expiratory positive airway pressure intranasal resistance valve
	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)
	E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)
	E0601	Continuous positive airway pressure (cpap) device

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.

- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
3/2023	Changed AIM Speciality Health to Carelon
8/2023	Criterion addressing Adaptive Servo-Ventilation (ASV) devices added.
1/2024	Interim Update. Added non covered criterion for upper airway resistance syndrome.
3/2024	Interim Update. Updated criteria for ASV devices.