Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Kentucky Only)

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Instructions for Use

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Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

See Benefit Considerations

For Durable Medical Equipment (DME), orthotics, Medical Supplies, and repairs/replacements, refer to the Kentucky Administrative Regulations 907 KAR 1:479 Durable Medical Equipment Covered Benefits and Reimbursement for coverage criteria.

Contact Lenses & Scleral Bandages (Shells)

Contact lenses or scleral shells that are used to treat an Injury or disease (e.g., corneal abrasion, keratoconus, or severe dry eye) are not considered DME and may be covered under the 907 KAR 1:632. Vision Program.

Repair and Replacement

For DME repair and replacement, refer to the Kentucky Administrative Regulations 907 KAR 1:479 Durable Medical Equipment Covered Benefits and Reimbursement for coverage criteria.

Ventilators and Respiratory Assist Devices

Note: The medical necessity clinical coverage criteria below only applies to persons 2 years of age and older. Ventilators and Respiratory Assist Devices are covered without further review for persons younger than 2 years of age.

Ventilators are covered to treat neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.

For member's 2 years of age and older ventilators are not covered when used only to deliver continuous or intermittent positive airway pressure for adults and children. Any type of ventilator would not be Medically Necessary when:

- The ventilator is used only in a bi-level PAP (HCPCS codes E0470 and E0471) mode.
- Used for conditions that qualify for use of a Respiratory Assistance Device (RAD) that are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death.
- Ventilators, such as Trilogy mechanical ventilators (HCPCS codes E0465 and E0466), used for the treatment of conditions that deliver continuous or intermittent positive airway pressure are not Medically Necessary.

Mechanical ventilators (HCPCS codes E0465 and E0466) are considered medically necessary in certain clinical scenarios. For medical necessity clinical coverage criteria, refer to the InterQual® Medicare: Post Acute & Durable Medical Equipment, Ventilators.

Click here to view the InterQual® criteria

Bi-level positive airway pressure (BiPAP) devices (HCPCS codes E0470 and E0471) are considered medically necessary in certain clinical scenarios. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Noninvasive Airway Assistive Devices.

Click here to view the InterQual® criteria.

BiPAP device with or without backup rate is considered unproven and not medically necessary due to insufficient high-quality evidence of safety and efficacy for individuals with CSA and OSA when adherent use of BiPAP is for less than 4 hours during sleep time on at least 21 to 30 consecutive 24-hour periods.

For patients with COPD, BiPAP is considered unproven and not medically necessary due to insufficient high-quality evidence of safety and efficacy when an arterial $PaCO_2$ is less than 52 mmHg while awake, even when the asleep $PaCO_2$

is at 55 mmHg or more for at least 10 minutes, or asleep $PaCO_2$ increase of > 10 mmHg from baseline awake and > 50 mmHg for at least 10 minutes during sleep time.

Note:
- Ventilators must not be billed using codes for CPAP (HCPCS code E0601) or bi-level PAP (HCPCS codes E0470, E0471, and E0472). The use of CPAP or bi-level PAP HCPCS codes to bill a ventilator is incorrect coding, even if the ventilator is only being used in CPAP or bi-level mode.

When determining medical necessity, clinical guidelines will be applied in the following order:
1. Federal, state, and contractual requirements.
2. InterQual® CP Durable Medical Equipment.
3. UnitedHealthcare Community Plan Medical Policy.
4. InterQual® Medicare Durable Medical Equipment.
5. CMS DME MAC.

Coverage Limitations and Exclusions

Refer to the Kentucky Administrative Regulations 907 KAR 1:479 Durable Medical Equipment Covered Benefits and Reimbursement for coverage limitations and exclusions.

Definitions

Durable Medical Equipment (DME): Medical Equipment that is all of the following:
- Withstands repeated use;
- Is primarily and customarily used to serve a medical purpose;
- Is generally not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home. (907 KAR 1:479)

Injury: Damage to the body, including all related conditions and symptoms.

Medical Supplies: Items that are:
- Consumable;
- Nonreusable;
- Disposable; and
- Primarily and customarily used to serve a medical purpose. (907 KAR 1:479)

Reasonable Useful Lifetime (RUL): RUL is the expected minimum lifespan for the item. It starts on the initial date of service and runs for the defined length of time. The default RUL for durable medical equipment is set at 5 years. RUL is also applied to other non-DME items such as orthoses and prostheses. RUL is not applied to supply items (Noridian, 2011).

Applicable Codes

UnitedHealthcare has adopted the requirements and intent of the National Correct Coding Initiative. The Centers for Medicare & Medicaid Services (CMS) has contracted with Palmetto to manage Pricing, Data and Coding (PDAC) for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). This notice is to confirm UnitedHealthcare has established the PDAC as a source for correct coding and coding clarification.

Benefit Considerations

Cranial Remolding Orthosis

Cranial molding helmets (cranial remolding orthosis, billed with S1040) used to facilitate a successful post-surgical outcome are covered. For all indications, refer to the Medical Policy titled Plagiocephaly and Craniosynostosis Treatment (for Kentucky Only).

Note: A protective helmet (HCPCS code A8000–A8004) is not a cranial remolding device. It is considered a safety device worn to prevent injury to the head rather than a device needed for active treatment.

Equipment Upgrades

- A change in the member's medical condition and equipment needs requires the same documentation as a new request
- Equipment upgrades are equivalent to a new service

Implanted Devices

Any device, appliance, pump, machine, stimulator, or monitor that is fully implanted into the body is not covered as DME. (If covered, the device is covered as part of the surgical service).

Cochlear Implant Benefit Clarification: The external components (i.e., speech processor, microphone, and transmitter coil) are considered under the DME benefit, and the implantable components are considered under the medical-surgical benefit.

Insulin Pumps

Insulin pumps, disposable and durable, are covered. For state specific information on mandated coverage of diabetes supplies, reference the federal, state, or contractual requirements. Refer to the Medical Policy titled Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Kentucky Only).

Lymphedema Stockings for the Arm

Post-mastectomy lymphedema stockings for the arm are considered DME. For state specific information on mandated coverage, reference the state or contractual requirements.

Trachea-Esophageal and Voice Aid Prosthetics

Trachea-esophageal prosthetics and voice aid prosthetics are covered as DME.

Clinical Evidence

Non-Invasive Airway Assistive Devices

Bi-level Positive Airway Pressure (BiPAP) Including Humidifiers

Due to insufficient evidence, BiPAP is considered unproven for patients with COPD when an arterial $PaCO_2$ is less than 52 mmHg while awake, even when the asleep $PaCO_2$ is at 55mmHg or more for at least 10 minutes, or asleep $PaCO_2$ increase of > 10 mmHg from baseline awake and > 50 mmHg for at least 10 minutes during sleep time.

In a Cochrane Review conducted by Pinto et al. (2022), the authors assessed the effectiveness and safety of non-invasive positive pressure ventilation (NIPV) for the treatment of adults with CSA. A search was conducted in the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, and Scopus. The search resulted in 15 RCTs which included 1936 participants. The authors found CPAP + best supportive care may reduce central AHI in patients with CSA associated with CHF, however it does not decrease the cardiovascular mortality. The available evidence is uncertain and no definitive conclusions could be drawn thus additional high-quality trials is warranted to determine whether NIPV is better than another mode or better than best supportive care. Future studies should focus on patient-centered outcomes, quality of life, quality of sleep and long-term survival.

In a multicenter RCT, Masa et al. (2019) sought to determine the long-term effectiveness of both CPAP and non-invasive ventilation therapy treatment modalities in patients with obesity hypoventilation syndrome. There were two phases of the study with an original 221 participants screened. The first phase was designed to assess the effect of the three different groups (non-invasive ventilation, CPAP and life-style changes) on daytime $PaCO_2$, quality of life, spirometry, 6-min walk distance (6-MWD), and polysomnography. The second phase of the study randomized 204 participants to either the non-invasive ventilation or CPAP group; these participants were followed for three years and instructed on lifestyle modification. In addition, supplemental oxygen therapy was added if baseline hypoxemia was identified. CPAP titration was done at time of conventional polysomnography; the mean continuous positive pressure setting was 10.7 cm H_2O. The initial non-invasive ventilation adjustment was completed during wakefulness. The expiratory positive airway pressure was set between 4 and 8 cm H_2O, and

the inspiratory positive airway pressure was set between 18 and 22 cm H_2O. Participants were evaluated at baseline, first and second months and every 3 months thereafter through two years and then every 6 months until completing year three. The authors concluded non-invasive ventilation and CPAP appear to have similar long-term efficacy, however CPAP may be the preferred first line treatment and therefore individual assessment is recommended.

Murphy et al. (2017) examined the effect of home noninvasive ventilation (NIV) plus oxygen in patients with persistent hypercapnia after an acute exacerbation of COPD. 116 participants were randomized to either receive home oxygen therapy + home noninvasive ventilation (n = 57) or home oxygen therapy alone (n = 59); between the two groups, eighteen patients withdrew from the trial. Noninvasive ventilation was initiated by using nasal, oronasal, or total face masks (per patient preference) and delivered using the Harmony 2 ventilator (Philips Respironics) or the VPAP IIISTa ventilator (ResMed). The goal was to achieve control of nocturnal hypoventilation with a high-pressure ventilation strategy. All patients were instructed to use oxygen therapy for at least 15 hours/day and was initiated at the lowest flow rate required to increase the PaO_2 level to greater than 60mm Hg. The group using ventilation was also directed to use the ventilator for a minimum of 6 hours nightly. The primary outcome was time to readmission or death within 12 months following randomization. Secondary outcomes included exacerbation frequency, change in PaO_2 and $PaCO_2$, change in control of sleep-disordered breathing, and health related quality of life. The results revealed the median time to readmission or death was 4.3 months in the home oxygen therapy + home noninvasive ventilation group versus 1.4 months in the home oxygen therapy alone group. There was not a significant difference between the two groups for the twelve-month mortality; 16 patients in the home oxygen therapy + home noninvasive ventilation group versus 19 patients in the home oxygen therapy alone group. The authors concluded the amount of time to readmission or death was prolonged when noninvasive ventilation was added to home oxygen therapy, which in turn supports screening patients with COPD following acute intervention and present home noninvasive ventilation as a valid option. Limitations included concern over the effectiveness of blinding because both patients and clinicians were able to identify the sham intervention, limiting the scientific justification. Additionally, provisions were made for patients that were part of the home oxygen therapy alone group to add noninvasive ventilation after reaching the primary outcome.

In a meta-analysis of RCTs, Liao et al. (2017) studied the efficacy of long-term noninvasive positive pressure ventilation (NPPV) in stable hypercapnic COPD patients with respiratory failure. A comprehensive search was conducted using the PubMed, Cochrane Library, Embase, OVID and the Chinese Biomedical Literature Database. 1,014 studies were found and seven studies with 810 subjects were identified and used for analysis. Two studies were shown to be at low risk of bias while five of the studies were unclear. The authors found long-term NPPV significantly decreased the $PaCO_2$ of COPD patients with chronic type II respiratory failure, but no significant difference was found in mortality, frequency of acute exacerbation, PaO_2, lung function, respiratory muscle function or exercise capacity. Limitations included the inability of blinding for NPPV, inconsistency in the quality of trials along with differences in the types of data and evaluation methods.

Zhou et al. (2017) investigated the effects of home NIV on stable COPD patients with chronic hypercapnic respiratory failure by using NIV ventilator equipped with built-in software. Patients were recruited from 20 respiratory units and consisted of 115 patients that were ≥ 40 years of age and deemed clinical stable. Participants were randomly assigned to either NPPV group (n = 57) or control group (n = 58). All patients received long term oxygen therapy (LTOT) via nasal cannula at a flow rate of 1–3 L/min to achieve oxygen saturation of ≥90% and usage was at least 15 hours per day. In the NPPV group, NIV was used on the home setting for at least 5 hours per day. The installed built-in software recorded the parameters. These parameters included estimation of leaks, inspiratory positive airway pressure [IPAP], expiratory positive airway pressure [EPAP], tidal volume, minute ventilation, respiratory rate, back-up frequency, and percentage of inspirations triggered by the patient. The primary endpoint was $PaCO_2$. Overall compliance to the NIV treatment went well and resulted in a mean time of NIV usage at 5.6 ±1.4h per day. When the authors compared results to the baseline data, they found a decrease in $PaCO_2$ for the intervention group versus the control group (−10.41 ±0.97 vs −4.32 ±0.68 mmHg, p = 0.03). The authors' concluded ventilators equipped with built-in software provided methodology for monitoring NPPV use at home, which could in turn increase compliance of NPPV use. The authors revealed three months usage of NPPV reduced the $PaCO_2$ in patients with chronic hypercapnic COPD. Limitations included lack of long-term outcomes.

Kuklisova et al. (2016) evaluated the effects of bilevel positive airway pressure (BiPAP) in patients with OSA and concurrent COPD. The aim of the study was to analyze early predictors of CPAP failure in patients and evaluate the effects of BiPAP for this high-risk group of patients. Eighty-four participants were included in the study; documentation reflected a mean AHI of 33.2, daytime capillary PO_2 of 9.0 kPa and PCO_2 of 5.5 kPa. CPAP treatment along with titration followed AASM guidelines. Follow-up visits included patient interviews along with questionnaire completion, equipment inspection and data retrieval, and patient weights. Primary CPAP failure was found in 23% of patients who were obese, had worsening lung function, a lower PO_2 and

higher PCO_2 while awake when compared to those who responded to CPAP. When the authors compared the CPAP group to the BiPAP group, patients requiring BiPAP had a higher BMI, lower FEV_1 and FEV_1/FVC and worse gas exchange while awake as evidenced by a lower capillary SpO_2 and lower PO_2, and a higher PCO_2. Limitations included retrospective design of study and performance of capillary analysis instead of arterial blood gas analysis.

Cowie et al. (2015) conducted the SERVE-HF trial which investigated the effects of adding adaptive servo-ventilation (ASV) to guideline based medical treatment for patients with central sleep apnea (CSA) and heart failure. 1325 patients with a left ventricular ejection fraction of 45% or less, an apnea–hypopnea index (AHI) of fifteen or more events per hour, and a large number of central events were randomly assigned to one of two groups; group one patients received medical treatment with ASV and group two patients received medical treatment alone (control). The primary outcomes analyzed were death, a lifesaving cardiovascular intervention (such as transplant), or an unplanned hospitalization for worsening chronic heart failure. The quality of life was assessed with the use of the EuroQol Group 5-Dimension Self-Report Questionnaire (EQ-5D). Patients were instructed to use the ASV device for at least 5 hours per night, 7 days per week and adherence was defined as an average of at least 3 hours per night. The goal was to get the AHI reduced to less than 10 events per hour within 14 days after starting ASV. Patients were seen after 2 weeks, again at 3 and 12 months and every year thereafter. Patients in the ASV group underwent polysomnography at each visit and data from ASV device was downloaded. The authors found that although the group of patients that received ASV therapy effectively treated their central sleep apnea, it did not show any significant improvements over the guideline-based medical treatment. Limitations included the unblinded design, which may have introduced bias, lack of female participants and the inability to generalize results of findings due to the patients selected had heart failure with reduced ejection fraction and therefore unable to apply results to those patients with a preserved ejection fraction.

A multicenter RCT investigated the effects of long-term NPPV use on 195 patients with advanced, stable hypercapnic COPD (Köhnlein et al. (2014)). Participants were randomized into the NPPV group (n = 102) or the control group (n = 93). Inclusion criteria consisted of patients aged 18 years or older with stable COPD, had a baseline $PaCO_2$ of 7 kPa or higher and a pH higher than 7.35. Exclusionary criteria consisted of patients with a body mass index (BMI) ≥ 35 kg/m², previously initiated NPPV, malignant co-morbidities, severe heart failure, unstable angina, and severe arrhythmias. The control group received optimized COPD therapy without NPPV; the intervention group received optimized COPD therapy plus NPPV. The intervention group was instructed to use NPPV for at least 6 hours/day, preferably during sleep, but daytime usage was accepted. After the first visit on day fourteen, additional follow-up consisted of 3, 6, 9, and 12 months. NPPV was targeted to reduce baseline $PaCO_2$ by 20% or more or achieve $PaCO_2$ values lower than 6.5 kPa. The authors found adding long-term use of NPPV to standard treatment improved the survival of patients with hypercapnic, stable COPD. The control group demonstrated a one-year mortality of 33% but only 12% for the intervention group. Limitations included recruitment difficulties, lack of masking, lacked long-term outcomes and sample size was not as large as intended.

Bhatt et al. (2013) evaluated 27 adults and postulated that patients with stable severe COPD and a $PaCO_2$ of < 52 mmHg may have their dyspnea reduced and quality of life improved with the use of NPPV. The participants were randomized into either the NPPV group (n = 15) or control group (n = 12). After randomization, the NPPV group was fitted for full face mask or nasal pillows and started on a BiPAP® Synchrony ventilator (Respironics Inc) with final pressures titrated. Patients were instructed to use the ventilator for at least six hours every night for the next six months. Follow-up was done by respiratory therapist every day for the first week with a daily phone call in addition to an onsite visit to assure optimal usage of the device; additional follow up included assessment at 6 weeks, 3 months and 6 months. Dyspnea was assessed using the Baseline Dyspnea Index and the Transitional Dyspnea Index (TDI), sleep quality was assessed using the Pittsburgh Sleep Quality Index and quality of life using the Chronic Respiratory Disease Questionnaire (CRQ). Data was obtained from the machine and used as part of the analysis. The authors found a significant improvement in the CRQ and TDI scores over time with application of NPPV in addition to a beneficial effect on PaO_2. The authors found that the use of the NPPV did show minor improvements in PaO_2 and quality of life and therefore it appears NPPV does have some benefit for patients with COPD. Limitations included small sample size including all males, lacked a sham arm and low compliance from participants. Future studies including larger sample size is warranted.

Blau et al. (2012) conducted a prospective double-blind, randomized trial to evaluate the efficacy and compliance of CPAP against Auto bi-level Pressure Relief-Positive Airway Pressure (ABPR-PAP) in patients with OSA. Thirty-five patients diagnosed with moderate to severe OSA were randomized into either the CPAP group (n = 18) or the ABPR-PAP group (n = 17). The same device (BiPAP® Auto with Bi-Flex®; Philips Respironics, Inc.) was used for both groups and AHI was the primary outcome determined by polysomnography before and after treatment. Assessment of compliance was measured at 2 and 12 weeks with

the machine's Encore Pro® Smartcard. The authors found after 3 months of use, the AHA decreased in the CPAP group to 4.4 ±5.3 per hour and in the ABPR-PAP group to 2.6 ±3.8 per hour; differences between the groups were not statistically significant and a compliance rate of 94% was achieved. While further research is required to determine which set of patients will benefit most from this therapy, the authors concluded ABPR-PAP is promising and may provide an effective treatment for patients with OSA. Limitations included small sample size, lack of long-term follow-up and patient population already familiar with CPAP use.

Powell et al. (2012) conducted an RCT with forty-eight patients to see if early intervention with an alternative device (auto-titrating, bilevel, and pressure flexing) would improve therapy outcomes when compared to standard CPAP in OSA patients with a poor initial CPAP experience. Inclusionary criteria consisted of patients with a confirmed diagnosis of OSA diagnosis, baseline AHI ≥ 15/h, and had a suboptimal facility-based attended CPAP titration according to standard clinical protocol with ≥ 3 hours of attempted titration data. Patients with previous CPAP or bilevel use were excluded. Following randomization, participants underwent PSG titration and then received their device with usage instructions for the next 90 days. Education and counseling occurred along with follow up at 30 and 90 days; adherence was monitored via the device's tracking capabilities and downloaded after one week, 30 and 90 days. ESS and the Fatigue Severity Scale (FSS) were used to assess subjective estimates of sleepiness and fatigue along with the Functional Outcomes of Sleep Questionnaire (FOSQ). The authors found there was no significant difference between the two groups when it came to device adherence therefore it felt the auto bilevel device was just as effective as CPAP therapy. Limitations included a pilot study with small sample size thus not powered to assess significant difference between the two groups in addition to lacking long-term outcomes.

Ballard et al. (2007) studies 204 patients with previously diagnosed OSA and noncompliance with CPAP. There were two phases to the study. Phase 1 evaluated standard interventions to improve therapy compliance, including mask optimization, heated humidification, topical nasal therapy, and sleep apnea education. Participants that were consistently non-compliant were moved into phase 2 of the study; participants were randomized into two groups which assessed compliance between standard CPAP versus flexible bilevel positive airway pressure (BiFlex). Out of the original 204 noncompliant participants, 49% became compliant demonstrating an average nightly use of > 4 hours. Of the 155 left, 104 agreed to continue to the second phase; fifty-three patients were randomized to CPAP and fifty-one randomized to BiFlex therapy. The authors found that twenty-five BiFlex patients were compliant with therapy after ≥ 90 days of treatment, as opposed to only fifteen of the CPAP patients. Following review of the data the authors concluded that a change to flexible bilevel airway pressure can achieve improved compliance in patients previously noncompliant with CPAP.

Respiratory Assist Device, Bi-Level Pressure Capability, with Backup Rate Feature

There is insufficient evidence for BiPAP device for individuals with CSA and OSA when adherent use of BiPAP is for less than 4 hours during sleep time on at least 21 to 30 consecutive 24-hour periods.

In a Cochrane Review conducted by Askland et al. (2020), the authors assessed the effectiveness of educational, supportive, and/or behavioral therapies in adults who have been diagnosed with OSA and prescribed CPAP. It was theorized that educational, supportive and behavioral interventions may help initiate and maintain regular and continued use of CPAP. A comprehensive literature search was conducted and returned forty-one studies (randomized, parallel-group, and controlled). The trials included just over nine thousand participants and were grouped into the following: a) education, b) a supportive intervention, c) behavioral intervention, and d) a mixed intervention which used all three techniques. Due to the uncertainty of the evidence, the authors were unable to determine whether educational interventions improved device usage or not, but there was a high level of confidence that behavioral interventions did show a clinically significant increase in hourly usage of the device when compared with usual care. In addition, there was moderate certainty of evidence that demonstrated supportive interventions had a positive effect.

In a Cochrane Review conducted by Yamamoto et al. (2019), assessment was conducted on the effects of positive airway pressure (PAP) therapy for people with heart failure who experience CSA. A search was conducted using the Cochrane Library, MEDLINE, Embase, and Web of Science Core Collection. Sixteen RCTs involving a total of 2125 participants were included for review. The trials included participants with heart failure and a reduced ejection fraction along with PAP therapy consisting of ASV or continuous PAP therapy for one to thirty-one months. The authors found the effects of PAP therapy was uncertain. While evidence was found to show that PAP therapy did not reduce the risk of cardiac-related mortality and rehospitalization, there was some indication that it may provide improvement in quality of life for heart failure patients with CSA. While these findings were limited by low- or very low-quality evidence, PAP therapy may be worth considering for individuals with heart failure to improve their quality of life.

Pépin et al. (2018) investigated adherence rates in patients with sleep apnea based on the type of positive airway pressure (PAP) device used and the switching of PAP modality over time. The study included 198,890 patients which were divided into three distinct groups: CPAP only (started on CPAP and stayed on CPAP, n = 189,724); ASV only (started on ASV and stayed on ASV, n = 8,957); and Switch (started on CPAP, switched to ASV, n = 209). Adherence was defined as device usage for ≥ 4 hours per night on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial use. Average usage per day was calculated by dividing the total number of hours used in the period by the number of days in the period, where the period was defined as day one to day thirty, day sixty, or day ninety, or to the end date of the specific therapy. Results identified in the Switch group showed AHI decreased significantly on ASV versus CPAP use. At 90 days, adherence rates were 73.8% and 73.2% in the CPAP only and ASV only groups. In the Switch group, CPAP adherence was 62.7%, improving to 76.6% after the switch to ASV. Mean device usage at 90 days was 5.27, 5.31, and 5.73 h/d in the CPAP only, ASV only, and Switch groups, respectively. The authors concluded treatment-emergent or persistent CSA during CPAP reduced therapy adherence, but adherence improved after switching from CPAP to ASV. Limitations included lack of demographic data, lack of comorbidity conditions, and lack of information on specific rationale from clinicians when switching patients from CPAP to ASV. Further studies, including RCTs, are needed to assess the effect of ASV in patients with persistent or treatment-emergent CSA during CPAP.

Arzt et al. (2013) performed a multicentre, randomized, open label, parallel group trial, to test whether ASV improves daytime cardiac function in patients with heart failure (HF), sleep disordered breathing (SDB) and quality of life (QoL) when compared to stable optimal medical management alone. Inclusion criteria consisted of participants aged 18 to 80 years of age, contained CHF (NYHA class II-III) an LVEF ≤ 40%, stable optimal medical therapy for at least four weeks and an AHI ≥ 20 events per hour as assessed by polysomnography. Seventy-two patients were randomly assigned to either the control group (optimal medical management for HF) or the ASV group (ASV therapy in addition to optimal medical management). For the ASV group, the expiratory positive airway pressure of the ASV device was set to the determined night CPAP titration. The minimum and maximum pressures were set and the default backup rate of the machine was used. The information was obtained and saved onto a smart card located in the device. The primary outcome of the trial was the change in left ventricular ejection fraction (LVEF) within 12 weeks of treatment. The ASV device was used daily for approximately 4.5 hours with a mean expiratory positive airway pressure of 8.1 ±1.7 cmH_2O and the maximum inspiratory positive airway pressure of 14.0 ±5.3 cmH_2O; automatic backup rate was used in all patients. The authors found the change in LVEF, was similar in both the ASV and control groups showing a modest improvement. In a sub-analyses of patients with OSA (n = 36) and CSA (n = 32), the change in LVEF was not significantly different between the ASV and the control group. For secondary outcomes, AHI and central AHI were decreased in the ASV group compared to the control group. It was concluded the trial supported that ASV was an effective treatment for both CSA and OSA patients. Limitations included small sample size, changes in diuretic treatment for patients with worsening symptoms during the trial and the per-protocol (PP) analysis did not comply with the calculated sample size.

Dellweg et al. (2013) compared noninvasive positive pressure ventilation (NPPV) and anticyclic servo-ventilation (SV) in thirty patients that developed complex sleep apnea syndrome (CompSAS) during CPAP treatment. Participants were randomized into one of two groups: 1) standard NPPV ventilator, or 2) dynamic SV. After titration to the respective device, patients were told to use their device nightly during sleep and could contact the sleep center for any problems, however patients were not actively contacted by the facility during the treatment period of 6 weeks. Compliance was recorded from the machines. The authors found NPPV and servo-ventilation were able to suppress central and obstructive events during initial titration, but after six weeks SV was shown to be superior to NPPV. Limitations included small sample size, lack of blinding and occurrence of potential manual titration from patient.

Chowdhuri et al. (2012) conducted a retrospective review over 3 years on the management of CSA associated with varying comorbidities and opioid use for patients and report the effectiveness of titration with PAP (used alone or in conjunction with oxygen). Three groups of patients were studied: CPAP only, CPAP + O_2 and BPAP + O_2. The CSA treatment protocol consisted of positive pressure titration initiated at CPAP 4-5 cm H_2O and titrated upward to 10-14 cm H_2O. If frequent central apneas persisted at the designated CPAP pressures of 10-14 cm H_2O, then no further increase of CPAP occurred, but instead oxygen was introduced. If central apneas persisted despite the addition of supplemental O_2, CPAP was switched to BPAP while maintaining oxygen saturation ≥ 93%. There was an optimal response in 127 of the 151 patients following the protocol; in addition, the most effective common therapeutic modality was CPAP which occurred in 48% of the patients. Reduction in AHI and CAI was achieved in each group. In twelve patients, the addition of oxygen did not eliminate central apnea adequately (CAI > 5/h) despite attaining adequate oxygen saturation. The authors concluded CPAP therapy was effective in 50% of the population studied, supplemental oxygen therapy with PAP was effective in an additional 35% of cases, narcotic use was very common in patients with CSA and a more common risk factor for CSA than heart failure, and finally, PAP with added oxygen

therapy was effective in patients with CSA and opioid drug use and may be considered as alternative therapy when central apneas are not eliminated by CPAP alone. Limitations included the design of the study, use of BPAP spontaneous mode without a back-up rate, lack of REM sleep which if induced might have eliminated some of the central events and the inability to confirm amounts of opioids ingested.

Clinical Practice Guidelines

American Academy of Sleep Medicine (AASM)

The American Academy of Sleep Medicine commissioned a task force of board-certified sleep medicine specialists and experts with proficiency in the use of PAP in adults with OSA to develop recommendations based on a systematic review of the literature (Patil et al., 2019). The AASM Board of Directors made the following recommendations:

- Recommend that clinicians use PAP, compared to no therapy, to treat OSA in adults with excessive sleepiness. (STRONG)
- Suggest that clinicians use PAP, compared to no therapy, to treat OSA in adults with impaired sleep-related quality of life. (CONDITIONAL)
- Suggest that clinicians use PAP, compared to no therapy, to treat OSA in adults with comorbid hypertension. (CONDITIONAL)
- 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)
- Recommend that clinicians use either CPAP or APAP for ongoing treatment of OSA in adults. (STRONG)
- Suggest that clinicians use CPAP or APAP over BPAP in the routine treatment of OSA in adults. (CONDITIONAL)
- Recommend that educational interventions be given with initiation of PAP therapy in adults with OSA. (STRONG)
- Suggest that behavioral and/or troubleshooting interventions be given during the initial period of PAP therapy in adults with OSA. (CONDITIONAL)
- Suggest that clinicians use telemonitoring-guided interventions during the initial period of PAP therapy in adults with OSA. (CONDITIONAL)

American Thoracic Society (ATS)

For patients with chronic hypercapnic respiratory failure due to COPD, the ATS makes the following recommendations in a clinical practice guideline on long-term non-invasive ventilation (Macrea et al., 2020):

- Suggest the use of nocturnal noninvasive ventilation (NIV) in addition to usual care for patients with chronic stable hypercapnic COPD (conditional recommendation, moderate certainty).
- Suggest that patients with chronic stable hypercapnic COPD undergo screening for obstructive sleep apnea before initiation of long-term NIV (conditional recommendation, very low certainty).
- Suggest not initiating long-term NIV during an admission for acute-on-chronic hypercapnic respiratory failure, favoring instead reassessment for NIV at 2–4 weeks after resolution (conditional recommendation, low certainty).
- Suggest not using an in-laboratory overnight polysomnogram (PSG) to titrate NIV in patients with chronic stable hypercapnic COPD who are initiating NIV (conditional recommendation, very low certainty).
- Suggest NIV with targeted normalization of $PaCO_2$ in patients with hypercapnic COPD on long-term NIV (conditional recommendation, low certainty).

After considering the overall very low quality of the evidence, the ATS states CPAP rather than noninvasive ventilation be offered as the first-line treatment to stable ambulatory patients with obesity hyperventilation syndrome (OHS) and coexistent severe obstructive sleep apnea (Mokhlesi et al., 2019).

Department of Veterans Affairs (VA)/Department of Defense (DoD)

The 2019 guideline for the management of chronic insomnia disorder and OSA makes the following recommendations for treatment and management of OSA:

- Recommend individuals with OSA on positive airway pressure therapy use the treatment for the entirety of their sleep period(s).
- Continue usage of positive airway pressure therapy for patients with OSA even if treatment use is < 4 hours per night.
- Recommend educational, behavioral, and supportive interventions to improve positive airway pressure adherence.
- Offer interventions to improve positive airway pressure adherence upon initiation of therapy.

The following recommendations may help with adherence to PAP usage:

- Use of heated humidification.
- Ensure appropriate mask choice.
- Educational strategies.
- Cognitive behavioral therapies.
- Investigate and address high leakage issues.
- Upon initial implementation of PAP, follow-up at 4 weeks or earlier to evaluate usage.

National Institute for Health and Care Excellence (NICE)

Nice (2021) recommends the following treatments for moderate and severe obstructive sleep apnea/hypopnea syndrome (OSAHS):

- CPAP is recommended as a treatment option for adults with moderate or severe symptomatic OSAHS.
- Offer fixed-level CPAP, in addition to lifestyle advice, to people with moderate or severe OSAHS.
- Consider auto-CPAP as an alternative to fixed-level CPAP in people with moderate or severe OSAHS if patient is unable to tolerate fixed-level CPAP.

NICE (2021) recommends the following on CPAP and non-invasive ventilation for people with COPD-OSAHS overlap syndrome:

- Consider continuous positive airway pressure (CPAP) as first-line treatment for people with COPD–OSAHS overlap syndrome if they do not have severe hypercapnia ($PaCO_2$ of 7.0 kPa or less).
- Consider non-invasive ventilation instead of CPAP for people with COPD–OSAHS overlap syndrome with nocturnal hypoventilation if they have severe hypercapnia ($PaCO_2$ greater than 7.0 kPa).
- Offer face-to-face initial consultation within 1 month and subsequent follow-up according to the person's needs and until optimal control of symptoms, AHI or oxygen desaturation index (ODI), oxygenation and hypercapnia is achieved.
- When non-invasive ventilation or CPAP (with or without oxygen therapy) has been optimized for people with COPD–OSAHS overlap syndrome, consider 6-monthly to annual follow-up according to the person's needs.

NICE (2018) recommends the following for non-invasive ventilation (NIV) and COPD exacerbations:

- Use NIV as the treatment of choice for persistent hypercapnic ventilatory failure during exacerbations despite optimal medical therapy.
- Recommend NIV be delivered in a dedicated setting, with staff that have been trained in its application, experienced in its use, and aware of the limitations.

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Policy History/Revision Information

Date	Summary of Changes
02/01/2024	**Coverage Rationale** • Updated instruction to clarify the *Kentucky Administrative Regulations 907 KAR 1:479 Durable Medical Equipment Covered Benefits and Reimbursement for Durable Medical Equipment (DME)* should be referenced for coverage criteria for durable medical equipment, orthotics, medical supplies, and repairs/replacements ***Ventilators and Respiratory Assist Devices (applies for 2 years of age and older)*** • Updated language pertaining to medical necessity clinical coverage criteria; replaced reference to the "InterQual® Medicare: Durable Medical Equipment, Ventilators" with "InterQual® Medicare: *Post Acute &* Durable Medical Equipment, Ventilators" • Added language to indicate: o A BiPAP device with or without backup rate is considered unproven and not medically necessary due to insufficient high-quality evidence of safety and efficacy for individuals with CSA and OSA when adherent use of BiPAP is for less than 4 hours during sleep time on at least 21 to 30 consecutive 24-hour periods o For patients with COPD, a BiPAP device is considered unproven and not medically necessary due to insufficient high-quality evidence of safety and efficacy when an arterial $PaCO_2$ is less than 52 mmHg while awake, even when the asleep $PaCO_2$ is at 55 mmHg or more for at least 10 minutes, or asleep $PaCO_2$ increase of > 10 mmHg from baseline awake and > 50 mmHg for at least 10 minutes during sleep time **Benefit Considerations** • Added content/language (relocated from the *Coverage Rationale* section of the policy) pertaining to: o Cranial remolding orthosis o Equipment upgrades o Implanted devices o Insulin pumps o Lymphedema stockings for the arm o Trachea-esophageal and voice aid prosthetics **Supporting Information** • Added *Clinical Evidence* section • Updated *References* section to reflect the most current information • Archived previous policy version CS032KY.05

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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