Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements

Policy Number: RMHP.MP.009.31
Effective Date: March 1, 2025

Instructions for Use

Table of Contents **Page**

Related Policies

- Airway Clearance Devices
- Beds and Mattresses
- Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes
- Electrical and Ultrasound Bone Growth Stimulators
- Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation
- Enteral Nutrition (Oral and Tube Feeding)
- Hearing Aids and Devices Including Wearable, Bone-Anchored, and Semi-Implantable
- Home Traction Therapy
- Mechanical Stretching Devices
- Mobility Devices, Options, and Accessories
- Motorized Spinal Traction
- Obstructive and Central Sleep Apnea Treatment
- Omnibus Codes
- Patient Lifts
- Plagiocephaly and Craniosynostosis Treatment
- Pediatric Gait Trainers and Standing Systems
- Pneumatic Compression Devices
- Preventive Care Services
- Sleep Studies
- Supply Policy, Professional
- Speech Generating Devices

Coverage Rationale

See Benefit Considerations

Durable Medical Equipment (DME): Medical equipment that is all of the following:

- Ordered or provided by a physician for outpatient use primarily in a home setting
- Used for medical purposes
- Not consumable or disposable except as needed for the effective use of covered DME
- Not of use to a person in the absences of a disease or disability
- Serves a medical purpose for the treatment of a sickness or injury
- Primarily used within the home

Ventilators and Respiratory Assist Devices (Applies for 2 Years of Age and Older)

For members 2 years of age and older, ventilators are not medically necessary 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; or
- Used for conditions that qualify for use of a respiratory assistance devices (RAD) that are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death; or
- 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

Mechanical ventilators (HCPCS codes E0465 and E0466) are considered medically necessary to treat neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease in certain clinical scenarios. For medical necessity clinical coverage criteria, refer to the InterQual® Medicare: Post Acute & Durable Medical Equipment, Ventilators NCD.

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 central sleep apnea (CSA) and obstructive sleep apnea (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 chronic obstructive pulmonary disease (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 55mmHg or more for at least 10 minutes, or asleep $PaCO_2$ increase of > 10mmHg from baseline awake and > 50mmHg for at least 10 minutes during sleep time.

Medical Necessity Plans

In the absence of a related policy or coverage indication from above, UnitedHealthcare uses the following guidelines for medical necessity, applied in the following order:

- InterQual® CP: Durable Medical Equipment
- InterQual® Medicare: Post Acute & Durable Medical Equipment, Ventilators NCD
- Centers for Medicare & Medicaid Services (CMS) DME Medicare Administrative Contractor (MAC)

DME, related supplies, and orthotics are medically necessary when:

- Ordered by a physician; and
- The item(s) meets the plan's medically necessary definition (refer to the member specific benefit plan document); and
- Criteria are met (see above); and
- The item is not otherwise excluded from coverage

Definitions

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable definitions.

Customized: Items which are uniquely constructed or substantially modified for a specific member according to a physician's description and orders.
Conversely, items that:

- Are measured, assembled, fitted, or adapted in consideration of a patient's body size, weight, disability, period of need, or intended use (i.e., custom fitted items); or

- Have been assembled by a supplier, or ordered from a manufacturer, who makes available Customized features, modification or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician do not meet the definition of Customized items. These items are not uniquely constructed or substantially modified. The use of Customized options or accessories or custom fitting of certain parts does not result in a wheelchair or other equipment being considered as Customized. (CMS, 2013)

Durable Medical Equipment (DME): Medical Equipment that is all of the following:
- Ordered or provided by a Physician for outpatient use primarily in a home setting
- Used for medical purposes
- Not consumable or disposable except as needed for the effective use of covered DME
- Not of use to a person in the absence of a disease or disability
- Serves a medical purpose for the treatment of a sickness or injury
- Primarily used within the home (COC)

External Urinary Catheter: External urinary collection device (CMS, 2024).

Indwelling Urinary Catheter: A flexible plastic tube (a catheter) inserted into the bladder that remains there to provide continuous urinary drainage. (CMS, 2024)

Intermittent Urinary Catheter: The use of a flexible plastic tube (a catheter) inserted into the bladder to periodically drain the bladder. (CMS, 2024)

Irreparable: Deterioration of Durable Medical Equipment that is sustained from day-to-day usage over time and a specific event cannot be identified. Takes into consideration the Reasonable Useful Lifetime of the equipment. (CMS, 2021)

Reasonable Useful Lifetime (RUL): RUL is the amount of time that is considered standard for the reasonable use of Durable Medical Equipment (DME). The standard for DME is set at five (5) years. Computation of the useful lifetime is based on when the equipment is delivered to the member, not the age of the equipment. (CMS, 2021)

Women's Health and Cancer Rights Act of 1998, § 713 (a): "In general - a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits with respect to a mastectomy shall provide, in case of a participant or beneficiary who is receiving benefits in connection with a mastectomy and who elects breast reconstruction in connection with such mastectomy, coverage for (1) reconstruction of the breast on which the mastectomy has been performed; (2) surgery and reconstruction of the other breast to produce symmetrical appearance; and (3) prostheses and physical complications all stages of mastectomy, including lymphedemas in a manner determined in consultation with the attending physician and the patient." (WHCRA, 2023)

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 Analysis 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

Durable Medical Equipment (DME), and certain orthotics and supplies, are a covered health care service when the member has a DME benefit, the equipment is ordered by a physician to treat an injury or sickness (illness), and the equipment is not otherwise excluded in the member benefit plan document.

DME must be:
- Not consumable or disposable except as needed for the effective use of covered DME;
- Not of use to a person in the absences of a disease or disability;
- Ordered or provided by a physician for outpatient use primarily in a home setting; and
- Used for medical purposes.

Breast Pumps

Breast pumps may be covered under the preventive care services benefit. Refer to the Medical Policy titled Preventive Care Services for breast pump coverage indications.

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 as a therapeutic service. In these situations, contact lenses and scleral shells are not subject to a plan's contact lens exclusion.

Cranial Remolding Orthosis

Cranial molding helmets (cranial remolding orthosis, billed with HCPCS code S1040) are excluded except when they meet medical criteria. For all indications, refer to the Medical Policy titled Plagiocephaly and Craniosynostosis Treatment.

Note: A protective helmet (HCPCS codes 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; refer to the Coverage Limitations and Exclusions.

Enteral Pumps

Enteral pumps are covered as DME. Refer to the Medical Policy titled Enteral Nutrition (Oral and Tube Feeding) for information regarding formula.

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. The member specific benefit plan document must be referenced to determine if there are DME benefits for repair or replacement of external components.

Insulin Pumps

Insulin pumps, disposable and durable, are covered. Refer to the Medical Policy titled Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes.

Lymphedema Stockings for the Arm

Post-mastectomy lymphedema stockings for the arm are covered on an unlimited basis as to number of items and dollar amounts covered consistent with the requirements of the Women's Health and Cancer Rights Act (WHCRA) of 1998.

Medical Supplies

- Medical supplies that are used with covered DME are covered when the supply is necessary for the effective use of the item/device (e.g., oxygen tubing or mask, batteries for power wheelchairs and prosthetics, or tubing for a delivery pump).
- Ostomy supplies are limited to the following:
  - Irrigation sleeves, bags, and ostomy irrigation catheters
  - Pouches, face plates, and belts
  - Skin barriers

  Note: Benefits are not available for deodorants, filters, lubricants, tape, appliance cleaners, adhesive, adhesive remover, or other items not listed above.
- Urinary Catheters:
  - Benefits for External, Indwelling, and Intermittent Urinary Catheters for incontinence or retention
  - Benefits include related urologic supplies for Indwelling Catheters limited to:
    - Urinary drainage bag and insertion tray (kit)
    - Anchoring device
    - Irrigation tubing set
  - Documentation should include the number and type of catheters that are needed

Notes:
- Certain plans may exclude coverage for Urinary Catheters (e.g., test, drug, device, or procedure). Refer to the member specific benefit plan document to determine if this exclusion applies.
- Quantity limits may apply.

Orthotic Braces

Orthotic braces that stabilize an injured body part and braces to treat curvature of the spine are considered DME. (Refer to the Coverage Limitations and Exclusions.)

Examples of orthotic braces include but are not limited to:
- Ankle foot orthotic (AFO)
- Knee orthotics (KO)
- Lumbar-sacral orthotic (LSO)
- Necessary adjustments to shoes to accommodate braces
- Thoracic-lumbar-sacral orthotic (TLSO)

Note: There are specific codes that are defined by HCPCS as orthotics that UnitedHealthcare covers as DME.

Repair, Replacement, and Upgrade

Repair, replacement, and upgrade of DME is covered when the member has a DME benefit and any of the following:

Repair

The repairs, including the replacement of essential accessories, such as hoses, tubes, mouth pieces, etc., for necessary DME are covered when necessary to make the item/device serviceable.

Replacement

Replacement of DME is for the same or similar type of equipment which is beyond its Reasonable Useful Lifetime (RUL) and has become Irreparable.

Unless otherwise stated in this policy or in the member specific benefit plan document, DME has a RUL of 5 years:
- RUL does not apply to supply items necessary for the effective use of the DME item/device.
- Requests for exceptions are based on the member specific benefit plan document, medically necessary criteria, and are conducted on a case-by-case basis.

Upgrade

The physician provides documentation that the condition of the member changes (e.g., impaired function necessitates an upgrade to a power wheelchair from a manual one). Equipment upgrades require:
- For a change in the member's medical condition and equipment needs, the same documentation as a new request
- For equipment updates, the request will be treated as equivalent to a new service and require the same documentation

General Criteria

- Routine wear on the equipment renders it non-functional and the member still requires the equipment
  - Vendors/manufacturers are responsible for repairs, replacements, and maintenance for rented equipment and for purchased equipment covered by warranty.
  - Coverage includes DME obtained in a physician's office, DME vendor, or any other provider authorized to provide/dispense DME.
- Pediatric DME must allow room for growth adjustments to a minimum of 2 inches in seat width and 3 inches of seat depth
  Notes:
  - Growth method may not mean ordering equipment that it is too large for current needs.
  - A new prescription is not needed if the needs of the patient are the same.

Tracheo-Esophageal and Voice Aid Prosthetics

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

Positive Airway Pressure (PAP) Therapy

For the evaluation of PAP therapy, hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in airflow and with at least a ≥ 4% oxygen desaturation from pre-event baseline or the event is associated with an arousal (AASM Scoring Manual, 2023).

Coverage Limitations and Exclusions

When more than one piece of DME can meet the member's functional needs, benefits are available only for the item that meets the minimum specifications for member needs. Examples include but are not limited to:

- Standard electric wheelchair vs. custom wheelchair
- Standard bed vs semi-electric bed vs fully electric or flotation system
    - This limitation is intended to exclude coverage for deluxe or additional components of a DME item which are not necessary to meet the member's minimal specifications to treat an injury or sickness.

When the member rents or purchases a piece of DME that exceeds this policy, the member will be responsible for any cost difference between the piece he/she rents or purchases and the piece UnitedHealthcare has determined to be the most cost-effective.

The following services are excluded from coverage:

- Additional accessories to DME items or devices which are primarily for the comfort or convenience of the member are not covered; examples include but are not limited to:
    - Air conditioners
    - Air purifiers and filters
    - Batteries for non-medical equipment (e.g., flashlights, smoke detectors, telephones, watches, weight scales)
    - Humidifiers
    - Non-medical mobility devices (e.g., commercial stroller); this exclusion does not apply to pediatric wheelchairs
    - Remodeling or modification to home or vehicle to accommodate DME or patient condition (e.g., ramps, stair lifts and stair glides, wheelchair lifts, bathroom modifications, door modifications)
- Cranial molding helmets and cranial banding except when used to avoid the need for surgery and/or to facilitate a successful surgical outcome
- Dental braces
- Devices and computers to assist in communication and speech; however, for dedicated speech generating devices refer to the Medical Policy titled Speech Generating Devices
- Devices used specifically as safety items or to affect performance in sports-related activities
- Diagnostic or monitoring equipment purchased for home use (e.g., blood pressure monitor, oximeters) unless otherwise described as a covered health care service (e.g., oximeter use with a ventilator)
- Elastic splints, sleeves, or bandages, unless part of a covered health care service (e.g., sleeve used in conjunction with a lymphedema pump, or bandages used with complex decongestive therapy)
- Oral appliances for snoring
- Orthotic braces that straighten or change the shape of a body part
- Personal care, comfort, and convenience items and supplies; examples include but are not limited to:
    - Television
    - Telephone
    - Beauty/barber service
    - Guest service
- Powered and non-powered exoskeleton devices
- Prescribed or non-prescribed publicly available devices, software applications, and/or monitors that can be used for non-medical purposes (e.g., smart phone applications, software applications)
- Replacement of items due to malicious damage, neglect, or abuse
- Replacement of lost or stolen items
- Routine periodic maintenance (e.g., testing, cleaning, regulating, and checking of equipment) for which the owner or vendor is generally responsible
- The following items and supplies:
    - DME and supplies that are explicitly excluded in the member specific benefit plan document
    - Medical supplies (except those described above under Medical Supplies); this includes, but is not limited to bandages, gauze, dressings, cotton balls, and alcohol wipes
    - Items and supplies that do not meet the definition of a covered health care service
    - Ostomy supplies unless specifically stated as covered; refer to Medical Supplies
- The following items are excluded even if prescribed by a physician:

- Blood pressure cuff/monitor
- Enuresis alarm
- Non-wearable external defibrillator
- Trusses or girdle
- Ultrasonic nebulizers

- Upgrade or replacement of DME when the existing equipment is still functional; refer to the Repair, Replacement, and Upgrade section

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 PaCO2 increase of > 10mmHg from baseline awake and > 50mmHg 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 separate 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 ninety percent 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 level8 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 assess 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 PaCO2 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

References

Arzt M, Schroll S, Series F, et al. Auto-servoventilation in heart failure with sleep apnoea: a randomised controlled trial. Eur Respir J. 2013 Nov;42(5):1244-54.

Askland K, Wright L, Wozniak DR, et al. Educational, supportive and behavioural interventions to improve usage of continuous positive airway pressure machines in adults with obstructive sleep apnoea. Cochrane Database Syst Rev. 2020 Apr 7;4(4):CD007736.

Ballard RD, Gay PC, Strollo PJ. Interventions to improve compliance in sleep apnea patients previously non-compliant with continuous positive airway pressure. J Clin Sleep Med. 2007 Dec 15;3(7):706-12.

Bhatt SP, Peterson MW, Wilson JS, et al. Noninvasive positive pressure ventilation in subjects with stable COPD: a randomized trial. Int J Chron Obstruct Pulmon Dis. 2013;8:581-9.

Blau A, Minx M, Peter JG, et al. Auto bi-level pressure relief-PAP is as effective as CPAP in OSA patients--a pilot study. Sleep Breath. 2012 Sep;16(3):773-9.

Centers for Disease Control and Prevention. https://www.cdc.gov/growthcharts/clinical_charts.htm. Accessed June 6, 2024.

Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Heath Service. August 2021. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/bp102c15_0.pdf. Accessed June 6, 2024.

Centers for Medicare and Medicaid Services (CMS). New Healthcare Common Procedure Coding System (HCPCS) Codes for Customized Durable Medical Equipment. July 2013. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/MM8158.pdf. Accessed June 6, 2024.

Centers for Medicare and Medicaid Services (CMS). Urological Supplies. April 2023. Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33803. Accessed June 6, 2024.

Chowdhuri S, Ghabsha A, Sinha P, et al. Treatment of central sleep apnea in U.S. veterans. J Clin Sleep Med. 2012 Oct 15;8(5):555-63.

Cowie MR, Woehrle H, Wegscheider K, et al. Adaptive servo-ventilation for central sleep apnea in systolic heart failure. N Engl J Med. 2015 Sep 17;373(12):1095-105.

Dellweg D, Kerl J, Hoehn E, et al. Randomized controlled trial of noninvasive positive pressure ventilation (NPPV) versus servoventilation in patients with CPAP-induced central sleep apnea (complex sleep apnea). Sleep. 2013 Aug 1;36(8):1163-71.

Department of Veterans Affairs and the Department of Defense Clinical Practice Guideline for the management of chronic insomnia disorder and obstructive sleep apnea. Version 1.0. October 2019.

Dictionary.com. http://www.dictionary.com/browse/indwelling-catheter. Accessed May 24, 2023.

Ekkernkamp E, Kabitz HJ, Walker DJ, et al. Minute ventilation during spontaneous breathing, high-intensity noninvasive positive pressure ventilation and intelligent volume assured pressure support in hypercapnic COPD. COPD. 2014 Feb;11(1):52-8.

Köhnlein T, Windisch W, Köhler D, et al. Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised, controlled clinical trial. Lancet Respir Med. 2014 Sep;2(9):698-705.

Kuklisova Z, Tkacova R, Joppa P, et al. Severity of nocturnal hypoxia and daytime hypercapnia predicts CPAP failure in patients with COPD and obstructive sleep apnea overlap syndrome. Sleep Med. 2017 Feb;30:139-145.

Liao H, Pei W, Li H, et al. Efficacy of long-term noninvasive positive pressure ventilation in stable hypercapnic COPD patients with respiratory failure: a meta-analysis of randomized controlled trials. Int J Chron Obstruct Pulmon Dis. 2017 Oct 10;12:2977-2985.

Macrea M, Oczkowski S, Rochwerg B, et al. Long-Term Noninvasive Ventilation in Chronic Stable Hypercapnic Chronic Obstructive Pulmonary Disease. An Official American Thoracic Society Clinical Practice Guideline. Am J Respir Crit Care Med. 2020 Aug 15;202(4):e74-e87.

Masa JF, Mokhlesi B, Benítez I, et al. Long-term clinical effectiveness of continuous positive airway pressure therapy versus non-invasive ventilation therapy in patients with obesity hypoventilation syndrome: a multicentre, open-label, randomised controlled trial. Lancet. 2019 Apr 27;393(10182):1721-1732.

Medical and Surgical Supplies Coverage Determinations Medicare Coverage Issues Manual, Pub. 6, §60-9.

Mokhlesi B, Masa JF, Brozek JL, et al. Evaluation and Management of Obesity Hypoventilation Syndrome. An Official American Thoracic Society Clinical Practice Guideline. Am J Respir Crit Care Med. 2019 Aug 1;200(3):e6-e24.

Murphy PB, Rehal S, Arbane G, et al. Effect of home noninvasive ventilation with oxygen therapy vs oxygen therapy alone on hospital readmission or death after an acute COPD exacerbation: a randomized clinical trial. JAMA. 2017 Jun 6;317(21):2177-2186.

National Institute for Health and Care Excellence (NICE). NG115. Chronic obstructive pulmonary disease in over 16s: diagnosis and management. July 2018.

National Institute for Health and Care Excellence (NICE). NG202. Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s. August 2021.

Noninvasive Respiratory Support | American Academy of Pediatrics (aappublications.org) Accessed April 11, 2022.

Patil SP, Ayappa IA, Caples SM, et al. Treatment of adult obstructive sleep apnea with positive airway pressure: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2019 Feb 15;15(2):301-334.

Pépin JL, Woehrle H, Liu D, et al. Adherence to positive airway therapy after switching from CPAP to ASV: a big data analysis. J Clin Sleep Med. 2018 Jan 15;14(1):57-63.

Pinto ACPN, Rocha A, Pachito DV, et al. Non-invasive positive pressure ventilation for central sleep apnoea in adults. Cochrane Database Syst Rev. 2022 Oct 24;10(10):CD012889.

Powell ED, Gay PC, Ojile JM, et al. A pilot study assessing adherence to auto-bilevel following a poor initial encounter with CPAP. J Clin Sleep Med. 2012 Feb 15;8(1):43-7.

UnitedHealthcare Insurance Company Generic Certificate of Coverage 2018.

Women's Health and Cancer Rights Act of 1998. Available at: https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/whcra_factsheet.html. Accessed June 6, 2024.

Yamamoto S, Yamaga T, Nishie K, et al. Positive airway pressure therapy for the treatment of central sleep apnoea associated with heart failure. Cochrane Database Syst Rev. 2019 Dec 4;12(12):CD012803.

Zhou L, Li X, Guan L, et al. Home noninvasive positive pressure ventilation with built-in software in stable hypercapnic COPD: a short-term prospective, multicenter, randomized, controlled trial. Int J Chron Obstruct Pulmon Dis. 2017 Apr 27;12:1279-1286.

UnitedHealthcare Insurance Company Generic Certificate of Coverage 2018.

United Healthcare Insurance Company Individual Exchange Health Benefit Plan Generic Certificate of Coverage 2024.

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.