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

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➲ Instructions for Use

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Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

➲ See Benefit Considerations

This Medical Policy does not apply to Durable Medical Equipment or supplies used in an outpatient or inpatient facility.

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

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

Home mechanical ventilators are not medically necessary when:

- Used only in a bilevel positive airway pressure (PAP) mode (HCPCS codes E0470 and E0471); or
- Used for conditions that qualify for use of a respiratory assistance device that are not life-threatening conditions for which interruption of respiratory support would quickly lead to serious harm or death; or
- Used only to deliver continuous or intermittent PAP (HCPCS codes E0465 and E0466)

Home 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 (COPD) in certain clinical scenarios. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Durable Medical Equipment Home Mechanical Ventilation Devices: Invasive, Noninvasive, and Multifunction (Custom) – UHG.

Click here to view the InterQual® criteria.

Home mechanical ventilators are not medically necessary for individuals with stable COPD, with an arterial $PaCO_2$ of less than 52 mm Hg while awake on room air.

Bilevel PAP 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.

Due to insufficient evidence of safety and efficacy, bilevel PAP, with or without backup rate, is considered unproven and not medically necessary for individuals with central sleep apnea and obstructive sleep apnea when adherent use of bilevel PAP is for less than 4 hours during sleep time on at least 21 to 30 consecutive 24-hour periods.

Due to insufficient evidence of safety and efficacy, bilevel PAP is unproven and not medically necessary for individuals with COPD, with an arterial $PaCO_2$ of less than 52 mm Hg while awake on room air (even when the asleep $PaCO_2$ is at 55 mm Hg or more for at least 10 minutes or asleep $PaCO_2$ increase of > 10 mm Hg from baseline awake and > 50 mm Hg for at least 10 minutes during sleep time).

Medical Necessity Plans

In the absence of a related policy or coverage indication, 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
- 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

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the

member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

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 (WHCRA) of 1998, § 713 (a): A federal law that provides protections to individuals who choose to have breast reconstruction in connection with a mastectomy. If WHCRA applies to a patient and the patient is receiving benefits in connection with a mastectomy and the patient elects breast reconstruction, coverage must be provided for:

- All stages of reconstruction of the breast on which the mastectomy has been performed;
- Surgery and reconstruction of the other breast to produce a symmetrical appearance; and
- Prostheses and treatment of physical complications of all stages of the mastectomy, including lymphedema.

WHCRA does not require group health plans or health insurance issuers to cover mastectomies in general. If a group health plan or health insurance issuer chooses to cover mastectomies, then the plan or issuer is generally subject to WHCRA requirements (CMS WHCRA Factsheet, 2024).

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 but 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.

Dedicated Speech Generating Devices and Tracheo-Esophageal Voice Devices

Dedicated speech generating devices and tracheo-esophageal voice devices required for treatment of severe speech impairment or lack of speech directly due to sickness or injury may be covered as DME.

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.

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 3% decrease in oxygen desaturation from pre-event baseline or the event is associated with an arousal (AASM Scoring Manual, 2023).

Walkers

Walkers are proven and medically necessary in certain circumstances.

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, refer to the information on dedicated speech generating devices and tracheo-esophageal voice 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

Home Mechanical Ventilators

Home Mechanical Ventilators for Individuals With Chronic Obstructive Pulmonary Disease

Due to insufficient evidence, home mechanical ventilators (HMVs) are considered unproven for individuals with chronic stable chronic obstructive pulmonary disease (COPD) when arterial carbon dioxide pressure ($PaCO_2$) is less than 52 mm Hg while awake on room air.

Wu et al. (2022) conducted a systematic review and meta-analysis of 19 randomized controlled trials (RCTs) that involved 1,482 individuals to assess the effectiveness of long-term home noninvasive positive pressure ventilation (LTHNIPPV) in individuals with stable hypercapnic COPD. The study found that LTHNIPPV significantly reduced all-cause mortality compared with control treatments, with a relative risk (RR) of 0.76 (95% CI, 0.61-0.95; p = 0.02). It also lowered hospital admission rates, improved arterial oxygen pressure (PaO_2), reduced $PaCO_2$, and enhanced exercise capacity, dyspnea symptoms, and health-related quality of life. However, no significant improvement was observed in forced expiratory volume in 1 second (FEV_1) percent predicted. Importantly, a subgroup analysis revealed that individuals with a baseline $PaCO_2$ of ≥ 55 mm Hg had a greater mortality benefit (RR, 0.69; p = 0.02) than those with a $PaCO_2$ of < 55 mm Hg (RR, 0.87; p = 0.32). Similarly, individuals who achieved a greater reduction in $PaCO_2$ had a significantly lower mortality risk (RR, 0.42; p < 0.0001) than those with smaller reductions (RR, 0.91; p = 0.38). The study had limitations. First, variability in the definition of stable hypercapnia may have influenced results, although a subgroup analysis showed consistent findings and no significant heterogeneity in mortality outcomes, supporting their credibility. Second, differences in measurement tools and data types limited the pooling of some secondary outcomes, resulting in low-quality evidence. Third, the study quality varied, with many trials showing potential bias in selection, performance, and detection, which was considered in the evidence assessment. Lastly, while clinical trials suggest a link between $PaCO_2$ reduction and lower mortality, the underlying mechanisms remain unclear. The authors concluded that the initial $PaCO_2$ levels and their subsequent reduction may reflect the therapeutic impact of LTHNIPPV in individuals with stable hypercapnic COPD. To validate these findings, further large-scale, multicenter RCTs are warranted.

Wilson et al. (2020) conducted a comprehensive systematic review and meta-analysis to evaluate the impact of home noninvasive positive pressure ventilation (NIPPV) on clinical outcomes in individuals with COPD and hypercapnia. The $PaCO_2$ thresholds used to initiate NIPPV were associated with effect sizes for four primary outcomes: mortality, need for intubation, quality of life, and all-cause hospital admissions. The authors categorized $PaCO_2$ thresholds as 45 to 49 mm Hg, 50 to 51 mm Hg, and ≥ 52 mm Hg. Analyzing data from 21 RCTs and 12 observational studies that involved over 51,000 individuals, the study found that bilevel positive airway pressure (BPAP) was significantly associated with reduced mortality [odds ratio (OR), 0.66], fewer hospital admissions (OR, 0.22), and a lower need for intubation (OR, 0.34) compared with no device use. However, no significant improvement in quality of life was observed. Noninvasive HMVs also reduced hospital admissions but did not significantly affect mortality. BPAP was associated with stronger clinical benefits, possibly due to its superior ability to support ventilation and reduce $PaCO_2$ levels. The overall quality of evidence ranged from low to moderate, and many outcomes were based on a limited number of studies. These findings suggest that home NIPPV may improve survival and reduce healthcare utilization in individuals with hypercapnic COPD, although its effect on quality of life remains uncertain. Further high-quality research is needed to clarify these outcomes (Bhatt et al., included in this study).

Bhatt et al. (2013) conducted an RCT to investigate the effects of home NIPPV in participants with stable COPD who had a $PaCO_2$ level below 52 mm Hg, indicating normocapnia or mild hypercapnia. Overall, 30 participants with severe airflow limitation (FEV_1 < 50% predicted) were randomized to receive either NIPPV (BPAP at 15/5 cm H_2O) or usual care for 6 months. The study found that NIPPV led to modest improvements in dyspnea, particularly in Transitional Dyspnea Index scores at 6 weeks and 3 months, with sustained benefit in the Transitional Dyspnea Index-Task domain at 6 months. A small but statistically significant improvement in the Chronic Respiratory Questionnaire-Mastery domain of quality of life was observed. Importantly, while PaO_2 remained stable in the NIPPV group, it declined in the control group, suggesting a protective effect of NIPPV on oxygenation. The authors noted several strengths, including the focus on participants with stable COPD who were not significantly hypercapnic, which is an atypical target group for NIPPV. By excluding participants with sleep apnea, they aimed to isolate the effects of NIPPV on COPD-related outcomes and carefully monitored mask-related side effects. However, the study had limitations: it lacked a sham control arm, which may have introduced placebo effects; the control group consisted entirely of male participants, raising concerns about gender bias; and the study was underpowered to assess outcomes such as mortality and exacerbation rates. Additionally, participant adherence was low, likely due to the absence of pressure titration, a run-in period, and the nature of the intervention (issues common in similar studies). The study concluded that NIPPV may offer limited but meaningful benefits in quality of life and dyspnea for individuals with stable COPD with a $PaCO_2$ of < 52 mm Hg, warranting further research in this subgroup.

Noninvasive Airway Assistive Devices

Bilevel Positive Airway Pressure, Including Humidifiers

Due to insufficient evidence, BPAP is considered unproven for individuals with COPD when arterial $PaCO_2$ is less than 52 mm Hg while awake on room air (even when the asleep $PaCO_2$ is at 55 mm Hg or more for at least 10 minutes or asleep $PaCO_2$ increase of > 10 mm Hg from baseline awake and > 50 mm Hg 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 NIPPV for the treatment of adults with central sleep apnea (CSA). A search was conducted in the Cochrane Central Register of Controlled Trials, MEDLINE, Embase, and Scopus. The search resulted in 15 RCTs, which included 1,936 individuals. The authors found that continuous positive airway pressure (CPAP) plus best supportive care may reduce central Apnea-Hypopnea Index (AHI) in individuals with CSA that is associated with chronic heart failure; however, it does not decrease the cardiovascular mortality. The available evidence is uncertain, and no definitive conclusions could be drawn; therefore, additional high-quality trials are warranted to determine whether NIPPV is better than another mode or better than best supportive care. Future studies should focus on individual-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 noninvasive ventilation (NIV) therapy treatment modalities in participants 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 (NIV, CPAP, and lifestyle changes) on daytime $PaCO_2$, quality of life, spirometry, 6-minute walk distance, and polysomnography. The second phase of the study randomized 204 participants to either the NIV or CPAP group; these participants were followed up for 3 years and instructed on lifestyle modification. In addition, supplemental oxygen therapy was added if baseline hypoxemia was identified. CPAP titration was done at the time of conventional polysomnography; the mean continuous positive pressure setting was 10.7 cm H_2O. The initial NIV adjustment was completed during wakefulness. The expiratory positive airway pressure (PAP) was set between 4 and 8 cm H_2O, and the inspiratory PAP was set between 18 and 22 cm H_2O. Participants were evaluated at baseline, at the first and second

months, and every 3 months thereafter through 2 years and then every 6 months until completion of year 3. The authors concluded that NIV and CPAP appear to have similar long-term efficacy; however, CPAP may be the preferred first-line treatment. Thus, individual assessment is recommended.

Murphy et al. (2017) examined the effect of home NIV plus oxygen in participants with persistent hypercapnia after an acute exacerbation of COPD. Overall, 116 participants were randomized to either receive home oxygen therapy plus home NIV (n = 57) or home oxygen therapy alone (n = 59); between the two groups, 18 participants withdrew from the trial. NIV was initiated by using nasal, oronasal, or total face masks (per individual preference) and delivered using the Harmony 2 ventilator (Philips Respironics) or the VPAP III ST-A ventilator (ResMed). The goal was to achieve control of nocturnal hypoventilation with a high-pressure ventilation strategy. All participants were instructed to use oxygen therapy for at least 15 hours/day, which was initiated at the lowest flow rate required to increase the PaO_2 level to greater than 60 mm 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 that the median time to readmission or death was 4.3 months in the home oxygen therapy plus home NIV group vs 1.4 months in the home oxygen therapy alone group. There was not a significant difference between the two groups in 12-month mortality: 16 participants in the home oxygen therapy plus home NIV group vs 19 participants in the home oxygen therapy alone group. The authors concluded that the amount of time to readmission or death was prolonged when NIV was added to home oxygen therapy, which in turn supports the screening of individuals with COPD following acute intervention and presents home NIV as a valid option. Limitations include the concern over the effectiveness of blinding because both participants and clinicians were able to identify the sham intervention, limiting the scientific justification. Additionally, provisions were made for participants who were part of the home oxygen therapy alone group to add NIV after reaching the primary outcome.

In a meta-analysis of RCTs, Liao et al. (2017) studied the efficacy of long-term NIPPV in individuals with stable hypercapnic COPD with respiratory failure. A comprehensive search was conducted using PubMed, the Cochrane Library, Embase, Ovid, and the Chinese Biomedical Literature Database. Overall, 1,014 studies were found, and seven studies, with 810 individuals, 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 that long-term NIPPV significantly decreased $PaCO_2$ in individuals with COPD 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, and exercise capacity. Limitations include the inability of blinding for NIPPV, inconsistency in the quality of trials, and differences in the types of data and evaluation methods.

Zhou et al. (2017) investigated the effects of home NIV in participants with stable COPD with chronic hypercapnic respiratory failure by using an NIV ventilator that was equipped with built-in software. Participants were recruited from 20 respiratory units; 115 participants who were ≥ 40 years of age and deemed clinical stable were included. Participants were randomly assigned to either the NIPPV group (n = 57) or control group (n = 58). All participants received long-term oxygen therapy via nasal cannula at a flow rate of 1 to 3 L/min to achieve oxygen saturation of 90%, and usage was at least 15 hours per day. In the NIPPV 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 the estimation of leaks, inspiratory PAP, expiratory PAP, tidal volume, minute ventilation, respiratory rate, backup frequency, and percentage of inspirations triggered by the participant. The primary end point was $PaCO_2$. Overall adherence to the NIV treatment went well and resulted in a mean time of NIV usage at 5.6 ±1.4 hours per day. When the authors compared results with the baseline data, they found a decrease in $PaCO_2$ in the intervention group vs the control group (-10.41 ±0.97 vs -4.32 ±0.68 mm Hg; p = 0.03). The authors concluded that ventilators that were equipped with built-in software provided methodology for monitoring NIPPV use at home, which could in turn increase adherence of NIPPV use. The authors revealed that 3-month usage of NIPPV reduced $PaCO_2$ in participants with chronic hypercapnic COPD. Limitations include the lack of long-term outcomes.

Kuklisova et al. (2016) evaluated the effects of BPAP in individuals with obstructive sleep apnea (OSA) and concurrent COPD. The aim of the study was to analyze early predictors of CPAP failure in individuals and evaluate the effects of BPAP in this high-risk group of individuals. Overall, 84 individuals 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 American Academy of Sleep Medicine guidelines. Follow-up visits included individual interviews, along with questionnaire completion, equipment inspection and data retrieval, and individual weights. Primary CPAP failure was found in 23% of individuals who were obese, had worsening lung function, and had a lower PO_2 and higher PCO_2 while awake compared with those who responded to CPAP. When the authors compared the CPAP group with the BPAP group, individuals who required BPAP had a higher body mass index, lower FEV_1 and FEV_1/forced vital capacity, and worse gas exchange while awake, as evidenced by a lower capillary SpO_2, lower PO_2, and higher PCO_2. Limitations include the retrospective design of the study and performance of a capillary analysis instead of an 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 in participants with CSA and heart failure. Overall, 1,325 participants with a left ventricular ejection fraction (LVEF) of 45% or less, AHI of 15 or more events per hour, and large number of central events were randomly assigned to one of two groups; group one participants received medical treatment with ASV, and group two participants received medical treatment alone (control). The primary outcomes that were analyzed were death, a lifesaving cardiovascular intervention (such as transplant), or an unplanned hospitalization for worsening chronic heart failure. Quality of life was assessed using the EuroQol Group 5-Dimension Self-Report Questionnaire. Participants 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 reduce the AHI to less than 10 events per hour within 14 days after starting ASV. Participants were seen after 2 weeks, again at 3 and 12 months, and every year thereafter. Participants in the ASV group underwent polysomnography at each visit, and data from the ASV device were downloaded. The authors found that although the group of participants that received ASV therapy effectively treated their CSA, it did not show any significant improvements over the guideline-based medical treatment. Limitations include the unblinded design, which may have introduced bias; lack of female participants; and inability to generalize results of findings because the participants who were selected had heart failure with reduced ejection fraction. Thus, the results could not be applied to those participants with a preserved ejection fraction.

A multicenter RCT investigated the effects of long-term NIPPV use in 195 participants with advanced stable hypercapnic COPD (Köhnlein et al., 2014). Participants were randomized into the NIPPV group (n = 102) or the control group (n = 93). Inclusion criteria consisted of participants aged 18 years or older with stable COPD who had a baseline $PaCO_2$ of 7 kPa or higher and a pH higher than 7.35. Exclusion criteria consisted of participants with a body mass index of ≥ 35 kg/m², previous initiation of NIPPV, malignant comorbidities, severe heart failure, unstable angina, and severe arrhythmias. The control group received optimized COPD therapy without NIPPV; the intervention group received optimized COPD therapy plus NIPPV. The intervention group was instructed to use NIPPV for at least 6 hours/day, preferably during sleep, but daytime usage was accepted. After the first visit on day 14, additional follow-up consisted of 3, 6, 9, and 12 months. NIPPV was targeted to reduce the baseline $PaCO_2$ by 20% or more or achieve $PaCO_2$ values lower than 6.5 kPa. The authors found that adding long-term use of NIPPV to standard treatment improved survival in participants with hypercapnic stable COPD. The control group had a 1-year mortality of 33%, but this was only 12% in the intervention group. Limitations include recruitment difficulties, the lack of masking, the lack of long-term outcomes, and a sample size that was not as large as intended.

Blau et al. (2012) conducted a prospective, double-blinded, randomized trial to evaluate the efficacy of and adherence to CPAP against Auto Bi-Level Pressure Relief-Positive Airway Pressure (ABPR-PAP) in participants with OSA. Overall, 35 participants who were 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) was used for both groups, and AHI was the primary outcome, determined by polysomnography before and after treatment. Assessment of adherence was measured at 2 and 12 weeks with the machine's Encore Pro® Smartcard. The authors found that after 3 months of use, the AHI 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 an adherence rate of 94% was achieved. While further research is required to determine which set of participants would benefit most from this therapy, the authors concluded that ABPR-PAP is promising and may provide an effective treatment for individuals with OSA. Limitations include the small sample size, the lack of long-term follow-up, and a participant population that was already familiar with CPAP use.

Powell et al. (2012) conducted an RCT, with 48 participants, to see if early intervention with an alternative device (autotitrating, bilevel, and pressure flexing) would improve therapy outcomes compared with standard CPAP in participants with OSA with a poor initial CPAP experience. Inclusion criteria consisted of participants who had a confirmed diagnosis of OSA, baseline AHI of ≥ 15/hour, and suboptimal facility-based attended CPAP titration, according to standard clinical protocol, with ≥ 3 hours of attempted titration data. Participants with previous CPAP or bilevel use were excluded. Following randomization, participants underwent polysomnogram 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 1 week and 30 and 90 days. The Epworth Sleepiness Scale and Fatigue Severity Scale were used to assess subjective estimates of sleepiness and fatigue, along with the Functional Outcomes of Sleep Questionnaire. The authors found no significant difference between the two groups related to adherence; therefore, it seemed that the auto bilevel device was just as effective as CPAP therapy. Limitations include a pilot study with a small sample size; therefore, it was not powered to assess significant differences between the two groups. Additionally, the study lacked long-term outcomes.

Ballard et al. (2007) studied 204 participants with previously diagnosed OSA and nonadherence with CPAP. There were two phases of the study. Phase 1 evaluated standard interventions to improve therapy adherence, including mask

optimization, heated humidification, topical nasal therapy, and sleep apnea education. Participants who were consistently nonadherent were moved into phase 2 of the study; participants were randomized into two groups that assessed adherence between standard CPAP vs flexible bilevel positive airway pressure (BiFlex). Of the original 204 nonadherent participants, 49% became adherent and had an average nightly use of > 4 hours. Of the 155 left, 104 agreed to continue to the second phase; 53 participants were randomized to CPAP, and 51 were randomized to BiFlex therapy. The authors found that 25 BiFlex participants were adherent to therapy after ≥ 90 days of treatment, as opposed to only 15 of the CPAP participants. Following review of the data, the authors concluded that a change to flexible bilevel airway pressure can achieve improved adherence in individuals who were previously nonadherent with CPAP.

Respiratory Assist Device, Bilevel Pressure Capability, With Backup Rate Feature

Due to insufficient evidence, BPAP (with or without backup rate) is considered unproven for individuals with CSA or OSA when adherent use of BPAP is less than 4 hours during sleep time in at least 21 to 30 consecutive 24-hour periods.

In a Cochrane Review that was 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 41 studies (randomized, parallel group, and controlled). The trials included just over 9,000 individuals and were grouped into the following: (1) education, (2) a supportive intervention, (3) behavioral intervention, and (4) a mixed intervention that 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 showed a clinically significant increase in hourly usage of the device compared with usual care. In addition, there was moderate certainty of evidence that demonstrated that supportive interventions had a positive effect.

In a Cochrane Review that was conducted by Yamamoto et al. (2019), assessment was conducted on the effects of PAP therapy for people with heart failure who experience CSA. A search was conducted using the Cochrane Library, MEDLINE, Embase, and the Web of Science Core Collection. Sixteen RCTs, involving a total of 2,125 individuals, were included for review. The trials included individuals with heart failure and a reduced ejection fraction, along with PAP therapy that consisted of ASV or continuous PAP therapy for 1 to 31 months. The authors found that the effects of PAP therapy were 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 in individuals with heart failure and 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 individuals with sleep apnea based on the type of PAP device used and the switching of PAP modality over time. The study included 198,890 individuals, who 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 any time during the first 3 months of initial use. The 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 1 to day 30, day 60, or day 90 or to the end date of the specific therapy. Results that were identified in the switch group showed that AHI decreased significantly with ASV vs 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. The mean device usage at 90 days was 5.27, 5.31, and 5.73 hours/day in the CPAP-only, ASV-only, and switch groups, respectively. The authors concluded that treatment-emergent or persistent CSA during CPAP reduced therapy adherence, but adherence improved after switching from CPAP to ASV. Limitations include the lack of demographic data, lack of comorbid conditions, and lack of information on the specific rationale from clinicians when switching individuals from CPAP to ASV. Further studies, including RCTs, are needed to assess the effect of ASV in individuals with persistent or treatment-emergent CSA during CPAP.

Arzt et al. (2013) performed a multicenter, randomized, open-label, parallel-group trial to assess whether ASV improves daytime cardiac function in participants with heart failure and sleep-disordered breathing as well as quality of life compared with stable optimal medical management alone. Inclusion criteria consisted of participants aged 18 to 80 years of age who had congestive heart failure (New York Heart Association class II-III) with an LVEF of ≤ 40%; stable optimal medical therapy for at least 4 weeks; and an AHI of ≥ 20 events per hour, as assessed by polysomnography. Overall, 72 participants were randomly assigned to either the control group (optimal medical management for heart failure) or the ASV group (ASV therapy in addition to optimal medical management). For the ASV group, the expiratory PAP 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 LVEF within 12 weeks of treatment. The ASV device was used daily

for approximately 4.5 hours, with a mean expiratory PAP of 8.1 ±1.7 cm H_2O and a maximum inspiratory PAP of 14.0 ±5.3 cm H_2O; the automatic backup rate was used in all participants. The authors found that the change in LVEF was similar in both the ASV and control groups and showed a modest improvement. In subanalyses in participants with OSA (n = 36) and CSA (n = 32), the change in LVEF was not significantly different between the ASV and control groups. For secondary outcomes, AHI and central AHI were decreased in the ASV group compared with the control group. It was concluded that the trial supported that ASV was an effective treatment for both participants with CSA and OSA. Limitations include the small sample size, changes in diuretic treatment for participants with worsening symptoms during the trial, and a per-protocol analysis that did not comply with the calculated sample size.

Dellweg et al. (2013) compared NIPPV and anticyclic servo-ventilation in 30 participants who developed complex sleep apnea syndrome during CPAP treatment. Participants were randomized into one of two groups: (1) standard NIPPV ventilator or (2) dynamic servo-ventilation. After titration to the respective device, participants were told to use their device nightly during sleep and could contact the sleep center for any problems; however, participants were not actively contacted by the facility during the treatment period of 6 weeks. Adherence was recorded from the machines. The authors found that NIPPV and servo-ventilation were able to suppress central and obstructive events during initial titration, but after 6 weeks, servo-ventilation was shown to be superior to NIPPV. Limitations include the small sample size, lack of blinding, and occurrence of potential manual titration by the participant.

Chowdhuri et al. (2012) conducted a retrospective review over 3 years on the management of CSA associated with varying comorbidities and opioid use in patients and reported the effectiveness of titration with PAP (used alone or in conjunction with oxygen). Three groups of patients were studied: CPAP only, CPAP plus O_2, and BPAP plus O_2. The CSA treatment protocol consisted of positive pressure titration that was initiated at CPAP of 4 to 5 cm H_2O and titrated upward to 10 to 14 cm H_2O. If frequent central apneas persisted at the designated CPAP pressures of 10 to 14 cm H_2O, then no further increase of CPAP occurred; instead, oxygen was introduced. If central apneas persisted despite the addition of supplemental O_2, CPAP was switched to BPAP while maintaining an oxygen saturation of ≥ 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 the AHI and Central Apnea Index was achieved in each group. In 12 patients, the addition of oxygen did not eliminate central apnea adequately (Central Apnea Index > 5/hour), despite attaining adequate oxygen saturation. The authors concluded that (1) CPAP therapy was effective in 50% of the population that was studied; (2) supplemental oxygen therapy with PAP was effective in an additional 35% of cases; (3) narcotic use was very common in patients with CSA and a more common risk factor for CSA than heart failure; and (4) 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 include the design of the study; use of the BPAP spontaneous mode without a backup rate; lack of rapid-eye-movement sleep, which, if induced, might have eliminated some of the central events; and inability to confirm the 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 with no therapy, to treat OSA in adults with excessive sleepiness (STRONG)
- Suggest that clinicians use PAP, compared with no therapy, to treat OSA in adults with impaired sleep-related quality of life (CONDITIONAL)
- Suggest that clinicians use PAP, compared with no therapy, to treat OSA in adults with comorbid hypertension (CONDITIONAL)
- Recommend that PAP therapy be initiated using either auto-adjusted positive airway pressure (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 College of Chest Physicians (CHEST)

In August 2025, CHEST published a new fact sheet for NIV in the home for the treatment of COPD based on a new coverage document by the Centers for Medicare and Medicaid Services. The new criteria for coverage of NIPPV in the treatment of chronic respiratory failure consequent to COPD are as follows:

- Removal of the prior requirement to perform overnight oximetry to document nocturnal hypoxemia
- Patients with COPD are eligible:
  - If they have hypercapnia of $PaCO_2$ 52 mm Hg (based on arterial blood gas); or
  - If sleep apnea is not the predominant cause of hypercapnia (based on documentation); or
  - If either stable COPD or hypercapnia is present at least 2 weeks following their hospitalization after resolution of a COPD exacerbation
- Evaluation within 6 months of starting NIPPV and must show:
  - Normalization of $PaCO_2$; or
  - Stabilization of rising $PaCO_2$; or
  - 20% reduction in $PaCO_2$ from baseline; or
  - Improvement in symptoms associated with chronic hypercapnia
- An HMV is indicated if the patient:
  - Requires O_2 therapy of FiO_2 of 36% or 4L nasally
  - Requires ventilatory support for more than 8 hours/day; or
  - Requires the alarms or internal battery of an HMV
- Continued use of either a BPAP device or HMV requires usage of at least 4 hours/day on at least 70% of days each month

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 NIV (Macrea et al., 2020):

- Suggest the use of nocturnal 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 OSA 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 to 4 weeks after resolution (conditional recommendation, low certainty)
- Suggest not using an in-laboratory overnight polysomnogram 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 that CPAP, rather than NIV, should be offered as the first-line treatment for stable, ambulatory patients with obesity hyperventilation syndrome and coexistent severe OSA (Mokhlesi et al., 2019).

Canadian Thoracic Society

This 2021 practice guideline provides updated recommendations on long-term NIV for patients with severe COPD and chronic hypercapnic respiratory failure (FEV_1 < 50% predicted). It focuses on two groups: (1) stable patients with severe COPD and hypercapnia and (2) those with persistent hypercapnia following an acute exacerbation requiring NIV. The guideline was developed by a multidisciplinary panel and based on English-language RCTs that were published between June 2010 and November 2020. Studies that involved sleep apnea or obesity-related hypoventilation were excluded. Risk of bias was assessed using the Cochrane tool, and evidence certainty was rated using Grading of Recommendations Assessment, Development, and Evaluation.

- In patients with stable, severe COPD and chronic hypercapnic respiratory failure ($PaCO_2$ ≥ 52 mm Hg), it was suggested that long-term NIV be used to improve survival [strength of evidence (SOE): weak/conditional; low certainty]
- In patients with severe COPD on long-term oxygen therapy who remain significantly hypercapnic (persistent $PaCO_2$ ≥ 52 mm Hg) at least 2 weeks after discontinuing NIV for an acute exacerbation, it was suggested that long-term NIV be used to delay hospital readmission (SOE: weak/conditional; very low certainty)
- When applying long-term NIV to patients with COPD and chronic hypercapnic respiratory failure (persistent $PaCO_2$ ≥ 52 mm Hg), it was suggested that high-intensity NIV instead of low-intensity NIV be used to improve $PaCO_2$ (SOE: weak/conditional; low certainty)

- The guidelines did not recommend the use of volume-assured pressure-preset NIV over standard pressure-preset NIV in patients with COPD and chronic hypercapnic respiratory failure (SOE: strong; low certainty)

This guideline marked a significant shift from its 2011 stance and now offers a favorable (although weak/conditional) recommendation for long-term NIV in select patients with COPD with chronic hypercapnic respiratory failure. It emphasizes aligning therapy with patient preferences, especially when NIV is used for more than 5 hours daily, effectively reduces $PaCO_2$, and controls nocturnal hypoventilation. Further research is encouraged (Kaminska et al., 2021).

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

The 2025 guideline for the management of chronic insomnia disorder and OSA makes the following recommendations for the treatment and management of OSA:

The following recommendations may help with adherence to PAP usage:
- Provide education regarding OSA and the prescribed treatment modality
- Use of heated humidification
- Ensure appropriate mask choice
- Cognitive behavior therapies to modify distorted view of OSA, enhance adherence through the development of positive associations with PAP, and integrate structured social support mechanisms
- Investigate and address high leakage issues
- On 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 they are unable to tolerate fixed-level CPAP

NICE (2021) recommends the following on CPAP and NIV for people with COPD-OSAHS overlap syndrome:
- Consider CPAP as first-line treatment for people with COPD-OSAHS overlap syndrome if they do not have severe hypercapnia (PaCO2 of 7.0 kPa or less)
- Consider NIV instead of CPAP for people with COPD-OSAHS overlap syndrome with nocturnal hypoventilation if they have severe hypercapnia (PaCO2 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, Oxygen Desaturation Index, and oxygenation and hypercapnia is achieved
- When NIV or CPAP (with or without oxygen therapy) has been optimized for people with COPD-OSAHS overlap syndrome, consider follow-up every 6 months to annually, according to the person's needs

NICE (2018; updated 2019) recommends the following for NIV and COPD exacerbations:
- Use NIV as the treatment of choice for persistent hypercapnic ventilatory failure during exacerbations despite optimal medical therapy
- Recommend that NIV be delivered in a dedicated setting, with staff that have been trained in its application, are experienced in its use, and are aware of the limitations
- When someone is started on NIV, there should be a clear plan for what to do in the event of deterioration, and the maximum level of intervention should be agreed in advance

Swiss Society of Pulmonology

The Special Interest Group of the Swiss Society of Pulmonology issued conditional recommendations for initiating long-term NIV in patients with COPD. The Special Interest Group suggests the following recommendations (Janssens et al., 2020).
- Long-term NIV should be used in chronic, stable hypercapnic patients [$PaCO_2$ > 7 kPa (52.5 mm Hg)] with severe COPD
- Long-term NIV should be implemented after an acute episode of hypercapnic respiratory failure only if hypercapnia [$PaCO_2$ > 7 kPa (52.5 mm Hg)] persists 2 to 4 weeks after the acute episode
- The potential benefit of long-term NIV for a recurrent acute episode of hypercapnic respiratory failure without persistent hypercapnia at 2 to 4 weeks remains undetermined

- When implementing NIV in patients with COPD with chronic hypercapnic respiratory failure, settings should be adjusted to decrease $PaCO_2$ below 6.5 kPa (50 mm Hg) or reduce $PaCO_2$ levels by more than 20% of the baseline level
- When implementing NIV in patients with COPD with chronic hypercapnic respiratory failure, fixed-pressure support ventilation should be preferred to autotitrating modes as the first-choice mode

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Policy History/Revision Information

Date	Summary of Changes
02/01/2026	**Coverage Rationale** • Added language to indicate this policy does not apply to Durable Medical Equipment or supplies used in an outpatient or inpatient facility ***Home Mechanical Ventilators and Respiratory Assist Devices (Applies for 2 Years of Age or Older)*** • Added language to indicate home mechanical ventilators are not medically necessary for individuals with stable COPD with an arterial $PaCO_2$ of less than 52 mm Hg while awake on room air • Replaced language indicating: ○ "*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 listed criteria are met]" with "*home mechanical* ventilators are not medically necessary when [the listed criteria are met]" ○ "A bilevel PAP *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 bilevel PAP is for less than 4 hours during sleep time on at least 21 to 30 consecutive 24-hour periods" with "bilevel PAP, with or without backup rate, is considered unproven and not medically necessary due to insufficient evidence of safety and efficacy for individuals with central sleep apnea and obstructive sleep apnea when adherent use of bilevel PAP is for less than 4 hours during sleep time on at least 21 to 30 consecutive 24-hour periods" ○ "Bilevel PAP is *considered* unproven and not medically necessary due to insufficient *high-quality* evidence of safety and efficacy for *patients* with chronic obstructive pulmonary disease (COPD) *when an* arterial $PaCO_2$ *is* less than 52 mm Hg 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" with "bilevel PAP is unproven and not medically necessary due to insufficient evidence of safety and efficacy for *individuals* with chronic obstructive pulmonary disease (COPD), *with an* arterial $PaCO_2$ *of* less than 52 mm Hg while awake *on room air* (even when the asleep $PaCO_2$ is at 55 mm Hg or more for at least 10 minutes or asleep $PaCO_2$ increase of > 10 mm Hg from baseline awake and > 50 mm Hg for at least 10 minutes during sleep time)" • Revised list of uses for home mechanical ventilators that are not medically necessary; replaced "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" with "[ventilators] used *only* to deliver continuous or intermittent positive airway pressure (HCPCS codes E0465 and E0466)" • Revised language pertaining to medical necessity clinical coverage criteria for home mechanical ventilators (HCPCS codes E0465 and E0466): ○ Added reference to the InterQual® Client Defined, CP: Durable Medical Equipment Home Mechanical Ventilation Devices: Invasive, Noninvasive, and Multifunction (Custom) – UHG ○ Removed reference to the InterQual® Medicare: Post Acute & Durable Medical Equipment, Ventilators NCD ***Medical Necessity Plans*** • Revised list of guidelines UnitedHealthcare uses to determine medical necessity in the absence of a related policy or coverage indication [listed in the policy]: ○ Added InterQual® Medicare: Post Acute & Durable Medical Equipment ○ Removed InterQual® Medicare: Post Acute & Durable Medical Equipment, Ventilators NCD **Medical Records Documentation Used for Reviews**

Date	Summary of Changes

	• Added language to indicate:
	  ○ Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service
	  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews
	Definitions
	• Updated definition of "Women's Health and Cancer Rights Act (WHCRA) of 1998, § 713 (a)"
	Benefit Considerations
	Dedicated Speech Generating Devices and Tracheo-Esophageal Voice Devices
	• Replaced language indicating "tracheo-esophageal *prosthetics and* voice aid *prosthetics are* covered as Durable Medical Equipment (DME)" with "*dedicated speech generating devices and* tracheo-esophageal voice *devices required for treatment of severe speech impairment or lack of speech directly due to sickness or injury may be* covered as DME"
	Walkers
	• Added language to indicate walkers are proven and medically necessary in certain circumstances
	Coverage Limitations and Exclusions
	• Updated list of coverage exclusions; added instruction to refer to the *Dedicated Speech Generating Devices and Tracheo-Esophageal Voice Devices* section of the policy for information on devices and computers to assist in communication and speech
	Supporting Information
	• Updated *Clinical Evidence* and *References* sections to reflect the most current information
	• Archived previous policy version MP.009.34

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, 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.