National Coverage Analysis (NCA)	Proposed Decision Memo

NCA - Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure consequent to COPD (CAG-00465N) - Proposed Decision Memo

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Decision Summary

A. General

Respiratory assist devices (RADs) with bi-level capability, with or without a backup rate feature, are devices that use a non-invasive interface (mask) to deliver a higher level of airway pressure when the patient inhales than when the patient exhales. A backup rate feature enables the device to provide a prespecified respiratory rate if the patient's spontaneous respiratory rate decreases below a set number.

Compared with RADs, home mechanical ventilators typically have additional ventilatory modes, monitoring, ventilator control, and safety, alarm, and backup power features (batteries).

B. Proposed Nationally Covered Indications

I. Respiratory Assist Devices (RADs)

(a) Initial Coverage Criteria

(i) RAD with Backup Rate Feature

The Centers for Medicare & Medicaid Services (CMS) proposes to cover a RAD with backup rate feature in the home to deliver high intensity noninvasive ventilation (NIV) as treatment for an individual with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD). A RAD with backup rate feature must be utilized in the high intensity mode (IPAP > 20 cm H2O and backup respiratory rate of at least 14 breaths per minute). A RAD with backup rate feature is covered in the home for an initial 180-day period for individuals with COPD when all the following criteria are met:

- The individual exhibits persistent hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO2;
- Sleep apnea is not the predominant cause of the hypercapnia;
- The individual exhibits the physical and cognitive ability to support home ventilation or has a caregiver who can assist, and
- The individual demonstrates one of the following characteristics:
  - Stable COPD, defined as no increase in or new onset of more than one respiratory symptom (cough, sputum production, sputum purulence, wheezing, or dyspnea) lasting 2 or more days and no change of pharmacological treatment during the 4-week period before initiation of NIV, or
  - Persistent hypercapnia for at least 2 weeks post hospitalization after resolution of an exacerbation of COPD requiring acute NIV.

(ii) RAD without Backup Rate Feature

CMS proposes to cover a RAD without backup rate feature for an individual with CRF consequent to COPD who cannot tolerate high intensity NIV or for whom the backup rate feature is otherwise medically inappropriate. A RAD without backup rate feature is covered in the home for an initial 180-day period for individuals with COPD when all of the following criteria are met:

- The individual exhibits persistent hypercapnia as demonstrated by $PaCO_2 \geq 52$ mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO_2;
- Sleep apnea is not the predominant cause of the hypercapnia; and
- The individual exhibits the physical and cognitive ability to support home ventilation or has a caregiver who can assist.

(iii) RAD Upon Hospital Discharge

CMS proposes to cover a RAD with or without backup rate feature in the home immediately upon hospital discharge for an initial 180-day period for individuals with acute on CRF due to COPD, if the individual required a RAD within the 24-hour period prior to hospital discharge to avoid rapid symptom exacerbation or rise in $PaCO_2$. The type of RAD covered (with or without backup rate feature) must be the same as that used during the last 24 hours of the inpatient admission.

(b) Continuing Usage Criteria for a RAD

CMS proposes that individuals receiving initial coverage for a RAD as described in (i), (ii) or (iii) above must be re-evaluated by day 180 after receiving a RAD, and at least every 6 months thereafter, to establish that continued coverage by Medicare beyond the first 180-days is medically necessary. Medicare will not continue coverage into the 7th and succeeding months of therapy until the required re-evaluation is performed and establishes that continued coverage is medically necessary.

During a re-evaluation to establish that continued coverage is medically necessary, the practitioner must evaluate and verify that all the following usage requirements are achieved by the beneficiary in order to continue coverage of the device:

- Consistent use of the device for an average of at least 5 hours per 24-hour period, and
- One or more of the following clinical outcomes has been achieved:
    - a normalization of $PaCO_2$, or
    - a 20% reduction in $PaCO_2$ from baseline value, or
    - a reduction in COPD exacerbations requiring hospitalization due, at least in part, to device usage, or
    - an improvement of at least one of the following patient symptoms associated with chronic hypercapnia:
        - Øheadache
        - Øfatigue
        - Øshortness of breath
        - Øconfusion

Note, as described in (i) above, a RAD with backup rate feature must be utilized in the high intensity mode (IPAP > 20 cm H_2O and backup respiratory rate of at least 14 breaths per minute).

II. Home Mechanical Ventilators

(a) Initial Coverage Criteria

CMS proposes to cover a home mechanical ventilator (HMV) used in a volume targeted mode as treatment for an individual with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD) who exhibits certain clinical characteristics.

(i) An HMV is covered for an initial 180-day period for individuals with COPD when all of the following criteria are met:

- The individual exhibits persistent hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO2;
- Sleep apnea is not the predominant cause of the hypercapnia;
- The individual exhibits the physical and cognitive ability to support home ventilation or has a caregiver who can assist; and
- The individual demonstrates at least one of the following characteristics:
    - Requires oxygen therapy at an FiO2 ≥36% or ≥ 4L nasally, or
    - Requires ventilatory support for more than 8 hours per 24-hour period, or
    - Requires the alarms and internal battery of a HMV, because the patient is unable to effectively breathe on their own for more than a few hours and the unrecognized interruption of ventilatory support is likely to cause a life-threatening condition if the patient or caregiver cannot be otherwise alerted, or
    - None of the below are likely to be achieved with consistent use of a RAD with backup rate feature for 5 hours per 24-hour period during an adequate trial period because the patient's inspiratory pressure needs exceed the capabilities of a RAD as justified by the patient's medical condition:
        - normalization of PaCO2, or
        - a 20% reduction in PaCO2 from baseline value, or
        - a reduction in COPD exacerbations requiring hospitalization due, at least in part, to device usage has occurred, or
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            - Øshortness of breath
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(ii) Home Mechanical Ventilator Use Upon Hospital Discharge

CMS proposes to cover an HMV used in a volume targeted mode immediately upon hospital discharge for an initial 180-day period for individuals with acute on chronic respiratory failure due to COPD if the beneficiary's needs exceeded the capabilities of a RAD (with or without backup rate feature) and required usage of a ventilator within the 24-hour period prior to hospital discharge to avoid rapid symptom exacerbation or rise in PaCO2.

b) Continuing Usage Criteria for an HMV

CMS proposes that individuals receiving coverage for an HMV as described in (i) and (ii) above must be re-evaluated by day 180 after receiving an HMV, and at least every 6 months thereafter, to establish that continued coverage by Medicare beyond the first 180-days is medical necessity. Medicare will not continue coverage into the 7th and succeeding months of therapy until the required re-evaluation is performed and

establishes that continued coverage is medically necessary.

During a re-evaluation to establish that continued coverage is medically necessary, the practitioner must evaluate and verify that the HMV has been used for an average of at least 5 hours per 24-hour period in order to continue coverage of the device.

(c) Masks for HMVs

For those individuals who require the daily use of home mechanical ventilation used in a volume targeted mode for greater than 8 hours per 24-hour period and use an oronasal mask at night, we are proposing to cover, in addition, either mouthpiece ventilation or nasal mask for use during day hours. Note, coverage of such supplies does not exclude coverage of additional supplies used for HMV necessary for the effective use of the HMV.

C. Nationally Non-Covered Indications

N/A

D. Other

Coverage of all other indications for RADs and HMVs used in the treatment of COPD, including subsequent attempts at their usage, not otherwise specified above as covered or non-covered, will be made by local Medicare Administrative Contractors under section 1862(a)(1)(A) of the Act.

See Appendix A for the proposed manual language.

Additionally, we propose to make conforming changes in Section 280.1 (Durable Medical Equipment List) of the National Coverage Determinations (NCD) Manual to add a cross reference to new NCD Section 240.9 (NIPPV in the Home for the Treatment of CRF Consequent to COPD).

CMS is seeking comments on our proposed decision pursuant to §1862(l)(3)(B) of the Act.

ProposedDecision Memo

TO: Administrative File: CAG-00465N

SUBJECT: Proposed National Coverage Determination for Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)

DATE: March 11, 2025

I. Proposed Decision

A. General

Respiratory assist devices (RADs) with bi-level capability, with or without a backup rate feature, are devices that use a non-invasive interface (mask) to deliver a higher level of airway pressure when the patient inhales than when the patient exhales. A backup rate feature enables the device to provide a prespecified respiratory rate if the patient's spontaneous respiratory rate decreases below a set number.

Compared with RADs, home mechanical ventilators typically have additional ventilatory modes, monitoring, ventilator control, and safety, alarm, and backup power features (batteries).

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CMS proposes to cover a RAD without backup rate feature for an individual with CRF consequent to COPD who cannot tolerate high intensity NIV or for whom the backup rate feature is otherwise medically inappropriate. A RAD without backup rate feature is covered in the home for an initial 180-day period for individuals with COPD when all of the following criteria are met:

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(iii) RAD Upon Hospital Discharge

CMS proposes to cover a RAD with or without backup rate feature in the home immediately upon hospital discharge for an initial 180-day period for individuals with acute on CRF due to COPD, if the individual required a RAD within the 24-hour period prior to hospital discharge to avoid rapid symptom exacerbation or rise in PaCO2. The type of RAD covered (with or without backup rate feature) must be the same as that used during the last 24 hours of the inpatient admission.

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    - an improvement of at least one of the following patient symptoms associated with chronic hypercapnia:
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Additionally, we propose to make conforming changes in Section 280.1 (Durable Medical Equipment List) of the National Coverage Determinations (NCD) Manual to add a cross reference to new NCD Section 240.9 (NIPPV in the Home for the Treatment of CRF Consequent to COPD).

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II. Background

Throughout this document we use numerous acronyms, some of which are not defined as they are presented in direct quotations. Please find below a list of these acronyms and corresponding full terminology:

ABG – arterial blood gas
AECOPD – acute exacerbation of COPD
ATS - American Thoracic Society
CMS - Centers for Medicare & Medicaid Services
CO2 – carbon dioxide
COPD - Chronic obstructive pulmonary disease
CRF – chronic respiratory failure
DME - durable medical equipment
DME MAC – Durable Medical Equipment Medicare Administrative Contractor
DMERC – Durable Medical Equipment Regional Carrier
EPAP - expiratory positive airway pressure
ERS- European Respiratory Society
FDA - Food and Drug Administration
FEV1 - forced expiratory volume in 1 second
FVC - forced vital capacity
GOLD - Global Initiative for Chronic Obstructive Lung Disease
GRADE – Grading of Recommendations, Assessment, Development and Evaluation
HMV – home mechanical ventilator
HRQoL – health related quality of life
IPAP - inspiratory positive airway pressure
ISO - International Organization of Standardization
LCD - Local Coverage Determination
LTH-NIV – long term home noninvasive ventilation
LTOT - long term oxygen therapy
NCA - National Coverage Analysis

NCD - National Coverage Determination
NIPPV- noninvasive positive pressure ventilation (also known as NPPV)
NIV – noninvasive ventilation
O2 – oxygen
PaO2 – partial pressure of O2 in the arterial blood
PaCO2 – partial pressure of CO2 in the arterial blood
PICO – patients, intervention, comparator, outcome
RAD - respiratory assist device
RCT – randomized controlled trial
SOE – strength of evidence
US - United States

Chronic Obstructive Pulmonary Disease

The GOLD Report, published by the 2023 Global Initiative for Chronic Obstructive Lung Disease (GOLD), defines chronic obstructive pulmonary disease (COPD) as… "a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnea, cough, expectoration, and/or exacerbations) due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction" (Agusti et al.,2023). COPD may have a multitude of causes, including genetic abnormalities, abnormal lung development, cigarette smoking, biomass and pollution exposure, lung infections, asthma, or the disease may be of unknown cause (Celli et al., 2022). It is a major cause of disability and is the third leading cause of death in the United States (Macrea & Coleman 3rd, 2022). It has been reported that of the Medicare population with coverage in 2018, 16.5% experienced COPD (Malla, Bodduluri, Sthanam, Sharma & Bhatt, 2023).

Though COPD is a chronic illness, affected individuals can periodically experience acute worsening of symptoms characterized clinically by increased dyspnea, cough, sputum production and sputum purulence. This acute worsening of symptoms has been termed acute exacerbation of COPD (AECOPD). COPD exacerbations are common and can result in lost work productivity, increased utilization of healthcare resources, temporary or permanent reductions in lung function and exercise capacity, hospitalization, and sometimes death (Kim & Aron, 2018). It has been shown that patients who have survived an acute episode of hypercapnic respiratory failure due to an exacerbation of COPD, have a poor prognosis with a high risk for readmission and death within a year (Ankjærgaard et al., 2016). In fact, COPD represents the third most common cause of hospital readmissions among Medicare beneficiaries (Coleman, Wolfe & Kalhan, 2019). Approximately 20% of Medicare beneficiaries hospitalized for acute exacerbations of COPD are readmitted within 30 days of discharge (Bhatt, Wells, Iyer et al., 2017).

Respiratory Failure

The respiratory system is responsible for the uptake of oxygen (O2) and the removal of carbon dioxide (CO2) from the body (Windisch, Geiseler, Simon, Walterspacher & Dreher, 2018). Respiratory insufficiency and subsequent failure are caused by impairment of gas exchange between the ambient air and the circulating blood and occurs when the pulmonary system cannot maintain a steady state of gas exchange in response to the metabolic demands of the body, resulting in the inadequate delivery of O2 and/or inadequate elimination of CO2 (Dekerlegand, Cahalin & Perme, et al., 2007).

The respiratory system consists of two parts: the lungs for gas exchange and a pump (the chest wall, respiratory muscles and the nervous system that controls the muscles) to ventilate or move air into/out of the lungs. In general, if there is failure of the gas exchange system, hypoxemia (low blood oxygen) results; failure of the "pump" leads to hypoventilation (which also causes hypoxemia) and hypercapnia (high levels of CO2 in the blood). Hypercapnia is the hallmark of ventilatory failure (Roussos & Macklem, 1982).

The ventilatory pump controls the volume of air moving in/out of the airways and the rate at which the air moves. Common measures used to evaluate airway function are forced vital capacity (FVC) and forced expiratory volume in one second (FEV1). FVC is the volume of air forcibly exhaled from maximal inspiration to maximal exhalation. FEV1 is the volume of air moved during the first second of the FVC maneuver and represents the air movement through the larger airways of the lungs (Dekerlegand et al., 2007). Spirometry is used to assess these measures and is needed to establish the diagnosis of COPD. Specifically, a forced vital capacity maneuver during spirometry showing the presence of a post-bronchodilator FEV1/FVC ratio < 0.7 is required for the diagnosis of COPD. Use of the ratio FEV1/FVC is not foolproof; yet in the appropriate context of symptoms and history of risk factors, the risk of misdiagnosis is limited. The FEV1 also serves to determine the severity of airflow obstruction (mild, moderate, severe, and very severe) (Agusti et al., 2023).

Arterial blood gases (ABGs) can also be used to examine the performance of the respiratory system. ABGs are measures of the partial pressure of O2 (PaO2), partial pressure of CO2 (PaCO2), levels of bicarbonate (HCO3) and the pH of the arterial blood. These factors are key to understanding the balance between the respiration (gas exchange between the alveolar air spaces and the blood) and ventilation processes. Hypoventilation (inadequate ventilation) causes PaCO2 to increase. This increase in PaCO2 will cause the blood pH to fall as it becomes more acidic (Dekerlegand et al., 2007).

COPD and Chronic Respiratory Failure with Hypercapnia

Chronic hypercapnia respiratory failure is common in severe COPD. Its prevalence ranges from 23%-38% (Macrea & Coleman, 2022). Patients with end-stage chronic hypercapnia secondary to COPD may experience fatigue, (morning) headache, loss of energy and dyspnea leading to impaired health-related quality of life (HRQoL) (van der Leest & Duiverman, 2019). They are also prone to repeated hospitalization with rapid clinical deterioration (Kaminska et al., 2021; Marwah, Dhar, Choudhary & Elliot, 2022). Moreover, compared to normocapnic patients, those who experience chronic hypercapnia from COPD have higher mortality rates (Daher & Dreher, 2020).

Noninvasive Positive Pressure Ventilation (NIPPV)

Non-invasive ventilation (NIV) is the application of ventilatory support through a non-invasive interface, usually a nasal or oronasal mask (Raveling, Vonk & Struik, et al. 2021). Currently the most frequently used form of NIV is positive pressure ventilation (Csoma, Vulpi & Dragonieri, et al., 2022), a treatment strategy that is often attempted to correct the respiratory impairments in COPD. NIV can be delivered in-facility or more chronically, at home. Though home therapy is generally applied at night (Rabec, Rodenstein, Leger et al., 2011), in patients with COPD the resultant blood gas changes can extend to the daytime hours (Orr, Azofra & Tobias, 2020).

Ventilation that is applied with positive pressure (higher than atmospheric pressure) pushes air or a mixture of oxygen combined with other gases into the lungs (Home Ventilator Guide, 2017; Potchileev, Doroshenko & Mohammed, 2023). Although the exact mechanism of benefit may not be known, noninvasive positive pressure ventilation (NIPPV) appears to reduce the effort needed to breathe by promoting respiratory muscle rest, enhancing both tidal volumes (the amount of inspired/expired air in each breath) and muscle fiber dynamics and reducing lung hyperinflation. Through these actions the use of NIPPV is thought to lead to improved elimination of carbon dioxide (Hatipoglu & Aboussouan, 2022).

For the administration of NIPPV in general, it is possible to choose from a selection of equipment including continuous positive airway pressure (CPAP) devices, bi-level positive airway pressure (BPAP) devices (known as respiratory assist devices or RADs in Medicare) and home mechanical ventilators (HMVs) (Gudivada, Rajasurya & Spector, 2020).

A CPAP device is one that delivers a constant level of positive airway pressure throughout the entire respiratory cycle (inspiration and expiration) (Kelly, Higgins & Chandra, 2015). It is the standard treatment for obstructive sleep apnea (Pavwoski & Shelgikar, 2017). Whereas CPAP is a type of NIPPV, it is not the focus of this NCA. Instead, the majority of this analysis will emphasize bi-level ventilation.

Bi-level positive airway pressure (BPAP) devices provide inspiratory positive airway pressure (IPAP) during inhalation and expiratory positive airway pressure during exhalation (EPAP). The IPAP and EPAP settings can be adjusted separately, with the inspiratory positive airway pressure (IPAP) being the higher level of pressure delivered. The IPAP serves to support and/or augment the tidal volume, while EPAP is set at a lower value in order to maintain upper airway patency and prevent alveolar closure during expiration. The difference between these two values is known as the pressure support. When properly applied, these pressures increase the patient's inspiratory depth and quantity of inhaled air to improve ventilation (Kelly, Higgins & Chandra, 2015; Kelly & Selim, 2023; Macrea & Coleman, 2022).

There are two broad categories of devices that can deliver bi-level NIPPV: respiratory assist devices with bi-level pressure capability (RADs) and non-invasive home mechanical ventilators (HMVs). RAD devices are more common; they need to be plugged into the wall and the pressure that can be generated is limited. Compared with RADs, HMVs typically have additional ventilatory modes (discussed below), monitoring, ventilator control, and safety, alarm, and backup power features (batteries). These devices are classified as "life support devices" by the Food and Drug Administration (FDA)(Wilson et al., 2019; Wilson, et al. 2020; Macrea & Coleman, 2022; Singh & Cao, 2020; Orr, 2023).

In addition to choosing the appropriate type of equipment for any given patient, it is also important to determine the mode in which the equipment functions in order to provide ventilatory assistance. A ventilation mode is a predefined pattern of interaction between a patient and the ventilation equipment (Chatburn, 2009) and therefore determines how a home respiratory device augments patient respiratory effort (Hansen-Flaschen & Ackrivo, 2023). More simply put perhaps, the mode of ventilation determines whether the ventilator or the patient initiates breathing and whether it is the patient or the device that performs most of the work of breathing (Dekerlegand et al., 2007).

By convention, the most basic designation of a mode is whether it is pressure or volume controlled. Pressure control means that the ventilator attempts to deliver a predetermined pressure output despite respiratory system characteristics of resistance, elastance or inspiratory effort. Volume control means that the ventilator attempts to deliver volume or flow according to a predetermined output, independent of factors that include inspiratory effort or compliance/resistance of the respiratory system. Additionally, the ventilatory mode will characterize the breaths being allowed (spontaneous or mandatory), as well as their timing, manner of initiation and stoppage (Chatburn, 2009).

The simplest bi-level positive airway pressure mode is the spontaneous (S) mode. Inspiratory effort by the patient initiates an assisted breath to the fixed IPAP; there is no backup rate in the event the patient's spontaneous respiratory rate decreases. In contrast to the S mode, the spontaneous/timed (ST) mode guarantees mandatory, timed breaths by the device if the patient's spontaneous respiratory rate decreases below the set backup rate. The purpose of the backup rate feature of the ST mode is to ensure a minimum number of breaths per minute if the patient is unable to do so spontaneously. (Singh & Cao, 2020).

In addition to the bi-level pressure modes discussed above, some RADs can deliver hybrid modes of pressure and volume ventilation (Singh & Cao, 2020). Also, in addition to pressure control ventilation, HMVs can also deliver volume controlled and/or volume pre-set ventilation modes (Wilson et al., 2020).

The term NIV (noninvasive ventilation) is at times substituted for the terminology of NIPPV or NPPV (Pierson, 2009). In this NCD/NCA these three terms will be used interchangeably, depending on the preferences of the authors whose

work is being described. Because RADs and home mechanical ventilators can both be considered types of non-invasive positive pressure mechanical ventilator devices (Wilson et al., 2019), wherever possible, to avoid confusion in this NCA, each device will be identified purposefully by their specific terminology and/or characteristics.

III. History of Medicare Coverage

In 1998, the National Association for Medical Directors of Respiratory Care (NAMDRC) hosted a multi-disciplinary consensus conference to more clearly discern the appropriate indications for NIPPV therapy. During the conference, it was noted that additional research studies and clinical trials were necessary for the selection of appropriate candidates for this therapy and to determine outcomes of noninvasive positive pressure ventilation in patients with COPD. In part based on suggestions put forth by participants of the 1998 conference, the Durable Medical Equipment Medicare Administrative Contractors (DMACs, but then called Durable Medical Equipment Regional Carriers or DMERCs) developed a regional medical review policy for RADs effective October 1, 1999 (CAG-00052, 2001).

For a bi-level respiratory assist device to have been covered under the regional medical review policy at that time for patients with COPD, the treating physician was required to document in the patient's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc. Additionally, the policy for RADs used for COPD patients required that the patients meet all of the following criteria:

- An arterial blood gas carbon dioxide reading (PaCO2), done while awake and breathing the patient's usual FiO2, be ≥ 52 mm Hg, and
- Sleep oximetry demonstrating an oxygen saturation ≤ 88% for at least five continuous minutes, done while breathing the patient's usual FiO2, and
- Prior to initiating therapy, obstructive sleep apnea (and treatment with continuous positive airway pressure) had been considered and ruled out.

If all of the above criteria for patients with COPD were met, a RAD without backup rate feature could be covered. For COPD patients who qualified for a RAD without backup rate feature, if at a time no sooner than 61 days after initial issue and compliant use the treating physician believed the patient required a RAD with backup, then this device could be covered if all of the following criteria were met:

- An arterial blood gas PaCO2, repeated no sooner than 61 days after initiation of compliant use of the RAD without backup rate feature, done while awake and breathing the patient's usual FiO2, remained ≥ 52mm Hg;
- A sleep oximetry, repeated no sooner than 61 days after initiation of compliant use of a RAD without backup rate feature, and while breathing with the RAD without backup rate feature, demonstrated an oxygen saturation ≤ 88% for at least five continuous minutes, done while breathing oxygen at 2 LPM or the patient's usual FiO2 (whichever was higher);
- A signed and dated statement from the treating physician, completed no sooner than 61 days after initiation of the RAD without backup rate feature, declared that the patient has been compliantly using the RAD without backup rate feature (at least an average of 4 hours per 24 hour period) but that the patient was NOT benefiting from its use;
- A Medicare beneficiary statement completed by the patient no sooner than 61 days after initiation of the RAD without backup rate feature documented that specified coverage criteria had been met.

Interested parties expressed concern with this policy, and especially with the prerequisite trial waiting period of NIPPV without backup rate feature before use of a noninvasive ventilation with a backup for COPD patients. In 2001, the NCA decision memorandum for Noninvasive Positive Pressure RADs for COPD (CAG-00052N) examined the clinical evidence for the use of these devices in the cited disease with the expectation of establishing a national

coverage policy. Specifically, the question was asked if evidence existed to demonstrate that severely ill COPD patients should have direct placement on a RAD with a backup rate feature without first having a trial of a respiratory assist device without a backup rate feature. Despite a thorough search of the medical literature and review of all literature submitted by requestors, CMS was unable to find any studies directly related to this analytic question and no national coverage decision was issued on this topic. Instead, CMS has maintained contractor discretion for coverage of RADs for qualifying COPD patients (CAG-00052N, 2001; LCD-33800, 2021).

NCD 280.1, Durable Medical Equipment (DME) Reference List, provides for coverage of ventilators for the treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.

A. Current Request

CMS received a complete, formal request for a reconsideration of §280.1 of the National Coverage Determinations (NCD) Manual, (Pub. 100-03, Part 4, Chapter 1) regarding coverage of positive and negative pressure ventilators as part of the Durable Medical Equipment Reference List. This request was provided by the Optimum Noninvasive Ventilation Medicare Access Promotion Technical Expert Panel, consisting of representatives from the American College of Chest Physicians, the American Academy of Sleep Medicine, the American Association for Respiratory Care, and the American Thoracic Society.

CMS accepted the request for the indication of chronic obstructive pulmonary disease and believes the subject matter is best served by development of a new NCD section. Therefore, the scope of this NCA is limited to NIPPV in the home for the treatment of chronic respiratory failure (CRF) consequent to COPD and no other portion of NCD 280.1 will be evaluated.

The formal request letter can be viewed via the tracking sheet for this NCA on the CMS website at https://www.cms.gov/medicare-coverage-database/view/ncacal-tracking-sheet.aspx?ncaid=315&ncacaldoctype=all&status=all&sortBy=status&bc=17.

B. Benefit Category

Medicare is a defined benefit program. For an item or service to be covered by the Medicare program, it must fall within one of the statutorily defined benefit categories outlined in the Social Security Act. Both RADs and HMVs are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)).

IV. Timeline of Recent Activities

Date	Actions Taken
September 11, 2024	CMS posts a tracking sheet announcing the opening of the NCA. The first 30-day public comment period begins.
October 11, 2024	First public comment period ends. CMS receives 72 comments.
March 11, 2025	CMS posts proposed Decision Memorandum. Second 30-day public comment period begins.

V. Food and Drug Administration (FDA) Status

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d). Amended section 514 of the FD&C Act

allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements (Federal Register, 2024).

One such consensus standard, ISO 80601-2-79:2024: Medical electrical equipment Part 2-79, applies to the basic safety and essential performance of ventilatory support equipment, such as respiratory assist devices, used in the home environment for those individuals with ventilatory impairment. The ventilatory support equipment within the scope of this standard is intended for use of patients who have ventilatory impairment, the most fragile of whom would not likely experience injury with the loss of this artificial ventilation. An example of the pertinent patient population for whom these equipment standards would be applicable include those individuals with mild to moderate COPD. The equipment within the scope of this standard is not intended for patients who are dependent on artificial ventilation for their immediate life support and may be operated by non-healthcare personnel.

ISO 80601-2-72:2023, "Medical electrical equipment Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients," applies to the basic safety and essential performance of a ventilator intended for use in the home environment. This equipment is meant for those individuals who need differing levels of support from artificial ventilation, including patients who are ventilator dependent. This equipment is intended to be operated by non-healthcare personnel with varying degrees of training.

VI. General Methodological Principles

When making national coverage determinations (NCDs), CMS generally evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for beneficiaries. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the Agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in the CMS National Coverage Analysis Evidence Review Guidance Document, published August 7, 2024, or any successor document.

Public comments sometimes cite published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS responds in detail to the public comments on a proposed national coverage determination when issuing the final national coverage determination.

VII. Evidence

A. Introduction

This section provides a summary of the evidence we considered during our review. The evidence reviewed to date includes the published medical literature on noninvasive positive pressure ventilation (NIPPV) for COPD. For this national coverage analysis (NCA), we searched PubMed and Embase for published medical literature in the form of clinical trials, systematic reviews, meta-analyses, evidence-based guidelines and professional society recommendations to answer the evidence questions below.

B. Discussion of Evidence

1. Evidence Question(s)

Question 1: In the patient with chronic hypercapnic respiratory failure consequent to COPD, is the evidence sufficient to provide coverage of a RAD with backup rate feature for initial NIV support in the home when the individual either exhibits stable COPD or is status post a recent exacerbation of COPD?

Question 2: In the patient with chronic hypercapnic respiratory failure consequent to COPD, is the evidence sufficient to determine if there are any conditions under which coverage of an HMV is reasonable and necessary?

Question 3: In the patient with chronic hypercapnic respiratory failure consequent to COPD, is the evidence sufficient to establish a 180-day trial period to determine if the use of home NIPPV delivered either from a bi-level respiratory assist device or a HMV, is reasonable and necessary?

2. External Technology Assessments

Wilson M, Wang Z, Dobler C, Morrow A, Beuschel B, Alsawas M, Benkhadra R, Seisa M, Mittal A, Sanchez M, Daraz L, Holets S, Murad MH. Noninvasive Positive Pressure Ventilation in the Home. Project ID: PULT0717 (Prepared by the Mayo Clinic Evidence-Based Practice Center under Contract No. HHSA290201500013I_HHSA29032004T).
Rockville, MD: Agency for Healthcare Research and Quality. March 2019.
http://www.ahrq.gov/clinic/epcix.htm

This Technology Assessment (TA) was prepared, in part, as reference material for the CMS Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting, held virtually on July 22, 2020 (see Section 4-Medicare Evidence Development & Coverage Advisory Committee below). The purpose of the MEDCAC was to review the evidence specific to the home use of noninvasive positive pressure ventilation by patients with chronic respiratory failure consequent to COPD. The goal of the TA was to evaluate home NIPPV in adult patients with chronic respiratory failure secondary to a variety of diseases affecting the pulmonary system, in terms of initiation, continuation, effectiveness, adverse events, equipment parameters and required respiratory services. Only the results of the TA examining patients with chronic respiratory failure due to COPD are reported below.

The full document can be found at:
https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id108TA.pdf.

The authors searched the National Guideline Clearinghouse, MEDLINE, EMBASE, SCOPUS, Cochrane Central Registrar of Controlled Trials, Cochrane Database of Systematic Reviews, and Scopus from January 1, 1995 to November 6, 2019. Randomized and comparative nonrandomized studies (prospective and retrospective) that enrolled adults with chronic respiratory failure who used NIPPV for ≥ 1 month at home using an HMV, bi-levelpositive airway pressure [BPAP] device, or CPAP were evaluated. The outcomes of interest were compared between the NIPPV and usual care or another mode or type of NIV. Outcomes included mortality, hospitalization, need for intubation, quality of life, emergency department visits, intensive care unit admissions/readmissions, COPD exacerbations, activities of daily living, dyspnea, sleep quality, exercise tolerance and adverse events.

The TA did not report any conclusions specifically related to our Evidence Questions above. However, the TA did demonstrate the following for patients with COPD:

- No studies compared the initiation criteria among different devices (HMV vs. BPAP vs. CPAP).
- The criteria used to start NIPPV were variable and included differing laboratory parameters of hypercapnia, hypoxia or a combination of the two.
- No studies directly compared the outcomes of patients based on different criteria of device initiation or compared initiation criteria between different devices (HMV vs. BPAP vs. CPAP).
- Processes used to titrate NIPPV were variable and included targeting reduction in hypercapnia, reduction in hypoxia, and reduction in patient symptoms.
- In patients with stable COPD, BPAP was associated with lower mortality, higher quality activities of daily living and reduced dyspnea.
- In patients with recent exacerbations of COPD, BPAP was associated with the reduced need for intubation.
- HMV (compared individually with BPAP, CPAP or no device) was associated with significantly fewer hospital admissions.
- Mean device usage per day (BPAP and HMV) ranged from 4.5-9.0 hours.

Furthermore, though the evidence was limited, approximately one third of patients who use NIPPV via any device for any studied condition experienced non-serious adverse events such as facial rash, mucosal dryness, mask discomfort, etc. Based on direct comparisons, no significant differences in adverse events between devices or between devices and no device were found. However, the authors noted that the evaluation of adverse events was limited by the fact that most of the included studies did not evaluate adverse events and the majority of the rest did not use a consistent approach for reporting and evaluation.

3. Internal Technology Assessment

To answer our evidence questions, we identified relevant studies in PubMed and EMBASE by using a combination of pertinent search terms including such words as COPD, noninvasive positive pressure ventilation, home/ domiciliary, systematic review and meta-analysis. To ensure that we captured all the relevant articles, a search was conducted independently by the contractor International Consulting Associates (ICA) for the CMS Coverage and Analysis Group (CAG).

We also reviewed references submitted to us by commenters and performed a hand search of retrieved bibliographies to identify other applicable literature for our review.

We originally anticipated that we would evaluate systematic reviews/meta-analyses of randomized controlled and/or observational trials that compared the outcomes of treatment of domiciliary noninvasive ventilation for patients with COPD and hypercapnia with the outcomes of those patients who did not receive NIPPV in the home. However, as will be explained further below, the technique of delivering NIPPV has changed markedly over the last 20+ years. We found that the systematic reviews/meta-analyses pertinent to our evidence questions included a series of studies performed over an expansive time period that contained fundamental differences in management techniques, creating a significant level of clinical heterogeneity, and causing the conclusions of the reviewed literature to be of questionable significance to our needs. Therefore, we deemed it reasonable to exclude this type of literature from our review and rely instead on relevant randomized controlled trials (RCTs) and the expert opinions of physicians and other medical personnel as expressed through the recommendations of professional societies, clinical practice guidelines and the like to answer our evidence questions.

The patient population investigated was required to consist of either those individuals with stable COPD or those individuals' status post an acute exacerbation of previously diagnosed COPD. Trials in which these patient populations were mixed were not considered unless subgroup results were reported. We excluded literature in which patients with obstructive sleep apnea were studied, documented either by polysomnography or clinical evaluation. Outcomes were required to be followed for at least six months, with our primary interest directed towards

mortality/survival data as well as repeat exacerbation/hospitalization data. Other outcomes of interest included adherence to NIV therapy in the home as well as changes in PaCO2 and quality of life measures.

Comparators were standard /usual care. So as not to confound our results, we excluded trials in which the usual care comparator specified such treatments as exercise programs or pulmonary rehabilitation programs. However, because of the widespread need for long term oxygen therapy (LTOT) in patients with COPD, we did allow trials that evaluated NIPPV with/without the addition of this therapy.

There were no date constraints placed on the RCTs considered applicable to our evidence review. Professional society guidelines from 2019 forward were also consulted. Only English language literature was considered.

Below are two evidence tables. Table 1 contains data summarized from two articles pertaining to patients with stable COPD. Table 2 contains data also summarized from two articles, pertaining to patients with a recent exacerbation of COPD. Furthermore, in Section VII of this NCA are the summaries of four professional society guidelines and two professional society position papers, as well as the findings of a pertinent Medicare Evidence Development & Coverage Advisory Committee Meeting and supporting Technology Assessment. The full citation for these publications can be found in the bibliography of this proposed decision memorandum.

Table 1. Data Summary for Patients with Stable COPD (2 studies)

Reference Groups (N) Follow-up	**Initial device setting Backup rate (bpm) Prescribed use**	**Effectiveness outcome at follow-up, unless otherwise noted Intervention vs. Comparator**
Köhnlein et al., 2014 Study Goal: To investigate the effect of long term NPPV targeted to markedly reduce hypercapnia, on survival of patients with advanced, stable hypercapnia NIPPV (102) vs. optimal medical therapy (93) Mean age NPPV: 62.2+8.6; Control: 64.4 ± 8.0 Mean BMI: NPPV 24.8+ 5.8: Control: 24.5 +5.8 Follow-up: 12 months	Initial device setting: Pressure support targeted to reduce baseline $PaCO_2$ by ≥ 20% or achieve $PaCO_2$ values < 6.5 kPa. High backup rates were preferred, but assisted ventilation was also acceptable if patients could not tolerate high backup rates Mean backup rate (SD): 16.1 (3.6) Prescribed use: 6 hours/day	Hospitalization and mortality: **Mortality, n (%): 12 (12) vs. 31 (33), HR (95% CI) 0.24 (0.11–0.49) (P)** Emergency hospital admissions per patient, M (SD): 2.2 (10.2) vs. 3.1 (5.4) Change in lung function, Intervention-Comparator (95% CI): **$PaCO_2$, %: –5.1 (–6.8 to –3.4) p < 0.0001** PaO_2, %: 0.8 (–1.6 to 3.1) p = 0.53 **HCO_3, %: -3.0 (–4.6 to –1.5) p = 0.00018** FVC, %: –0.3 (–3.1 to 2.5) p = 0.83 RV/TLC, %: –0.2 (1.4 to 1.1) p = 0.81 **PH: 0.015 (0.025 to 0.004) p = 0.0056** Mean change in HRQoL scores, Intervention-Comparator (95% CI): **SF-36, General Health Perception: 8.6 (1.8-13.3), p = 0.0289** **SRQ summary: 5.6 (0.1–1.1) p =**

Reference Groups (N) Follow-up	Initial device setting Backup rate (bpm) Prescribed use	Effectiveness outcome at follow-up, unless otherwise noted Intervention vs. Comparator
		0.0445
Clini et al., 2002 Study Goal: Assess the effect of the addition of NIPPV to LTOT to LTOT alone on severity of hypercapnia, use of healthcare resources and HRQoL. NIPPV (43) vs. optimal medical therapy (47) Mean age NIPPV: 64 ±7; LTOT: 66 ±14 BMI NIPPV: 26±5 BMI LTOT: 5±6 Follow-up: 2 years	Initial device setting: S/T mode at the maximal tolerated IPAP and at an EPAP tolerated in the range of 2–5 cmH2O. Oxygen was added to achieve SaO_2 of 90%. Patients needed to spend >90% of recording time with SaO_2 ≥ 90% under NIPPV Backup rate: 8 Prescribed use: ≥ 5 hours/night	<u>Hospitalization and mortality:</u> Mortality rate, %: 18 vs. 17 Hospital admissions, M (SD): 0.9 (1.2) vs. 1.4 (2.3) NS (P) ICU admissions, M (SD): 0.2 (0.4) vs.0.4 (0.8) NS (P) Days in hospital, 3 years pre- vs. 2 years post-study start, Intervention vs. Comparator, treatment effect (95% CI): 6.996 (-4.30–18.29) p=0.2281 (P) <u>Lung function:</u> **$PaCO_2$ during usual oxygen breathing, Intervention - Comparator (95% CI): 4.270 (1.58–9.96) p = 0.002 (P)** PaO_2 during usual oxygen breathing: NS (P) PaO_2 and $PaCO_2$ during room air breathing: NS (P) FEV, % pred, M (SD): 27.5 (10.6) vs. 30.8 (11.1), NS VC, % pred, M (SD): 55.3 (18.2) vs. 59.8 (12.3); NS MIP, cmH_20, M (SD): 50.6 (20.6) vs. 48.1 (27.2) NS <u>Mean change in HRQoL scores, Intervention-Comparator (95% CI):</u> SRGQ: p = 0.554 NS (P) **MRF-28, treatment effect: 7.100 (0.13-0.47) p = 0.04 (P)** Sleep quality score (1 is best, 4 is worst): 0.31 (0.1–1.0) **MRC dyspnea: 0.600 (0.15–1.05) p = 0.013** 6MWD, meters: 183 (118) vs. 232 (111) NS
Köhnlein T, Windisch W, Köhler D, Drabik A, Geiseler J, Hartl S, Karg O, Laier-Groeneveld G, Nava S, Schönhofer B, Schucher B, Wegscheider K, Criée CP, Welte T. 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. doi: 10.1016/S2213-2600(14)70153-5. Epub 2014 Jul 24. PMID: 25066329.		

Reference Groups (N) Follow-up	Initial device setting Backup rate (bpm) Prescribed use	Effectiveness outcome at follow-up, unless otherwise noted Intervention vs. Comparator
Clini E, Sturani C, Rossi A, Viaggi S, Corrado A, Donner CF, Ambrosino N; Rehabilitation and Chronic Care Study Group, Italian Association of Hospital Pulmonologists (AIPO). The Italian multicentre study on noninvasive ventilation in chronic obstructive pulmonary disease patients. Eur Respir J. 2002 Sep;20(3):529-38. doi: 10.1183/09031936.02.02162001. Erratum in: Eur Respir J. 2002 Dec;20(6):1617. PMID: 12358325.		

Abbreviations: 6MWD: 6-minute walk distance; CRQ: Chronic Respiratory Disease Questionnaire; bpm: breaths per minute; FEV: forced expiratory volume; FVC: forced vital capacity; GARS: Groningen Activity and Restriction Scale; HADS: Hospital Anxiety and Depression scale; HCO_3: bicarbonate; HR: hazard ratio; HRQoL: health-related quality of life; ICU: intensive care unit; MIP: maximal inspiratory pressure; MRC: Medical Research Council; MRF-28: Maugeri Respiratory Failure questionnaire; NIF: negative inspiratory force; NIPPV: non-invasive positive pressure ventilation; $PaCO_2$: partial pressure of carbon dioxide; PH: pulmonary hypertension; PSQI: Pittsburgh Sleep Quality Index; RV/TLC: Residual volume/total lung capacity; SRI: Severe Respiratory Insufficiency questionnaire; SRQ: Severe Respiratory Questionnaire; S/T: spontaneous/timed; TDI: Transitional Dyspnea Index; VC: vital capacity.
Note: Intermediary outcomes before final follow-up were omitted from table. Significant differences between the Intervention and Comparator groups are in **bold**. All significant findings favor the Intervention group. [1]P after an outcome indicates that this is a primary outcome; all other outcomes are secondary or exploratory outcomes.

Table 2: Data Summary for Patients Post-Acute Exacerbation of COPD (2 studies)

Reference Groups Follow-up	Device setting Backup Rate (bpm) Prescribed use	Effectiveness Outcome Change (difference from baseline to follow-up) or Intervention vs. Comparator at follow-up, unless otherwise noted
Murphy et al., 2017 Study Goal: to investigate the effect of home NIV + oxygen on time to readmission/death in patients with persistent hypercapnia after an acute COPD exacerbation NIPPV (57) vs. long-term oxygen therapy (59) Mean age NIV: 66.4±10.2; Home Oxygen: 67.1±9.0 Mean BMI (median (IQR) NIV: 21.5 (18.8-24.5); Home Oxygen: 22.2(17.9-26.9)	Device setting: Daytime NIPPV acclimatization followed by nocturnal titration with O_2 entrained at the daytime prescription rate to achieve control of nocturnal hypoventilation with a high-pressure ventilation strategy. Backup rate: 14-16 Prescribed use: O_2 therapy ≥15 hours/daily (both groups); NIPPV ≥6 hours/nightly	<u>Hospitalization and mortality, aHR (95% CI):</u> **Risk of readmission or death: 0.49 (0.31-0.77) p = 0.002 (P)** **28-day readmission rate: 0.26 (0.11-0.61) p = 0.002** All-cause mortality: aHR: 0.67 (0.34-1.30) p = 0.23 **Acute COPD exacerbations per year: 0.66 (0.46-0.9) p = 0.03** <u>Lung function, mm Hg, Intervention-Comparator, adjusted (95% CI):</u> **Nocturnal transcutaneous CO_2: -10.7 (-16.4 to -5.1) p < 0.001** Daytime $PaCO_2$: −2.3 (−6.5 to 1.9) p = 0.28 Daytime PAO_2: −0.1 (−5.3 to 5.3) p = 0.99 <u>Treatment effects for HRQoL, Intervention-Comparator, adjusted (95% CI):</u> SRI: −0.4 (−5.4 to 4.7) p = 0.89 SGRQ (high is worse): 2.3 (−2.6 to 7.1) p = 0.36

Reference Groups Follow-up	Device setting Backup Rate (bpm) Prescribed use	Effectiveness Outcome Change (difference from baseline to follow-up) or Intervention vs. Comparator at follow-up, unless otherwise noted
Follow-up: Median (IQR): NIV: 12.2 months (8.9-12.9) vs. Home oxygen:8.1 months (2.3-12.6		
Struik et al. 2014 Goal of Study: To investigate if nocturnal NIV in COPD patients with prolonged hypercapnia after acute respiratory failure increases the time to readmission for respiratory causes or death NIPPV (101) vs. optimal medical therapy (100) Mean age NIV:63.9± 8.6; Controls: 63.5±7.9 Mean BMI NIV: 24.4 ±5.4; Controls : 24.8+6.3 Follow-up: 12 months	Device setting: BIPAP S/T with a low backup rate of 12 bpm and an IPAP of 14 cm H_2O that was gradually increased to a maximal tolerated level. EPAP was started at 4 cm H_2O and increased if auto-PEEP was present or when patients used respiratory muscles to trigger the ventilator. The respiratory rate was set as close as possible to that of the patient. Inspiration to expiration time was 1:3, with a short rise time and titrated on comfort and effectiveness. Backup rate: 12 (initially) Prescribed use: 5 hours/night	Hospitalization and mortality: **Recurrent severe COPD exacerbation with hypercapnic ARF resulting in NIPPV, intubation, or death, %: 38.5 vs. 60.2 p = 0.039 (P)** Mean days to hospitalization or death: 192 vs. 198 p = 0.85 Hospital readmissions, median (range): 1 (0-9) vs. 1 (0-6) p = 0.23 Total days in the hospital, median (range): 7.0 (0–107) vs. 3.5 (0–77) p = 0.087 Exacerbations at home, median (range): 1.0 (0–9) vs. 2.0 (0–14) p = 0.26 Mean change in lung function, Intervention-Comparator (95% CI): **PH: 0.030 (0.005 to 0.050) p < 0.05** $PaC0_2$, kPa: −0.2 (−0.6 to 0.3) NS $Pa0_2$, Pa: −0.3 (−1.2 to 0.6) NS $HC0_3$, mmol/L: 1.0 (−1.2 to 3.3) NS Base excess: 1.0 (−0.8 to 2.8) NS Saturation (%):−0.5 (−3.9 to 2.8) NS FEV1, liters: −0.024 (−0.12 to 0.07) NS VC, liters: −0.036 (−0.31 to 0.23), NS HRQoL score treatment effects (95% CI): CCQ total: −0.04 (−0.5 to 0.4) NS MRF-28 total: −1.5 (−8.6 to 5.7) NS CRQ total: 0.01 (−0.4 to 0.4) NS SRI total: 4.8 (−0.1 to 9.7) NS GARS total: 0.4 (−2.3 to 3.0) NS HADS total: −1.3 (−4.1 to 1.6) NS MRC dyspnea: −0.05 (−0.6 to 0.5) NS

Murphy PB, Rehal S, Arbane G, Bourke S, Calverley PMA, Crook AM, Dowson L, Duffy N, Gibson GJ, Hughes PD, Hurst JR, Lewis KE, Mukherjee R, Nickol A, Oscroft N, Patout M, Pepperell J, Smith I, Stradling JR, Wedzicha JA, Polkey MI, Elliott MW, Hart N. 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. doi: 10.1001/jama.2017.4451. PMID: 28528348; PMCID: PMC5710342.

Struik FM, Sprooten RT, Kerstjens HA, Bladder G, Zijnen M, Asin J, Cobben NA, Vonk JM, Wijkstra PJ. Nocturnal non-invasive ventilation in COPD patients with prolonged hypercapnia after ventilatory

Reference Groups Follow-up	Device setting Backup Rate (bpm) Prescribed use	Effectiveness Outcome Change (difference from baseline to follow-up) or Intervention vs. Comparator at follow-up, unless otherwise noted

support for acute respiratory failure: a randomised, controlled, parallel-group study. Thorax. 2014 Sep;69(9):826-34. doi: 10.1136/thoraxjnl-2014-205126. Epub 2014 Apr 29. PMID: 24781217.

Abbreviations: aHR: adjusted hazard ratio; ARF: acute respiratory failure; bpm: breaths per minute; CCQ: Clinical COPD Questionnaire; CO_2: carbon dioxide; CPAP: continuous positive airway pressure; CRQ: Chronic Respiratory Disease Questionnaire; EPAP: expiratory positive airway pressure; GARS: Groningen Activity and Restriction Scale; HADS: Hospital Anxiety and Depression scale; HR: hazard ratio; HRQoL: health-related quality of life; IQR: interquartile range; IPAP: inspiratory positive airway pressure; LTOT: long-term oxygen therapy; MRF-28: Maugeri Respiratory Failure questionnaire; MRC: Medical Research Council; NIPPV: non-invasive positive pressure ventilation; O_2: oxygen; OMT: optimal medical therapy; $PaCO_2$: partial pressure of carbon dioxide; PaO_2: partial pressure of oxygen; PH: pulmonary hypertension SRI: Severe Respiratory Insufficiency Questionnaire; PEEP: positive end-expiratory pressure; SGRQ: St. George Respiratory Questionnaire.
Note: Intermediary outcomes before final follow-up were omitted from table. Significant differences between the Intervention and Comparator groups are in **bold.** All significant findings favor the Intervention group. ^{1}P after an outcome indicates that this is a primary outcome; all other outcomes are secondary or exploratory outcomes.

4. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

A virtual MEDCAC meeting was convened on July 22, 2020, to examine the scientific evidence pertaining to the use of various types of NIPPV equipment in order to assess the characteristics that define the patient selection criteria, usage parameters, concomitant services, and equipment parameters necessary to best achieve positive patient health outcomes in beneficiaries with CRF consequent to COPD. The devices considered were HMVs, BPAP devices and continuous positive airway pressure (CPAP) devices. The outcomes of interest included decreased mortality, decreased frequency of exacerbations requiring emergency room or hospital admission, increased time to hospital re-admission for respiratory related disease, and improved function and quality of life. The complete transcript of the meeting can be found at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/downloads/id77c.pdf.

Based on a score system where (1) indicates low confidence, (3) indicates intermediate confidence and (5) indicates high confidence, the MEDCAC Panel voted on the following questions to demonstrate their opinions on the evidence discussed during the meeting:

1. How confident are you that the evidence is sufficient to determine the patient selection criteria that will improve health outcomes (e.g. laboratory values, co-morbidities, frequency of exacerbations requiring ER or hospital admission, hospital discharge timing, pulmonary function tests, etc.) when used with any category of home NIPPV device? Overall average score = 3.15[1]
2. How confident are you that the evidence is sufficient to determine the NIPPV equipment parameters necessary to promote successful patient-related outcomes (e.g. decreased mortality, decreased frequency of exacerbations requiring ER or hospital admission, increased time to hospital re-admission for respiratory related disease, and improved physical function and quality of life)? Overall average score = 2.85
3. How confident are you that any improved patient–related outcomes noted above made with any type of NIPPV device in the home, can be attributed to the use of the equipment alone as opposed to the concomitant provision of other support services like home respiratory therapists, home medication reconciliation and repeated elective hospital admissions? Overall average score =2.23
4. How confident are you that the evidence is sufficient to provide the patient usage parameters that are necessary to achieve the successful patient outcomes in Q2? Overall average score = 2.38

Evidence-Based Guidelines

A search for evidence-based guidelines identified the following :

The European Respiratory Society Guideline

Ergan B, Oczkowski S, Rochwerg B, Carlucci A, Chatwin M, Clini E, Elliott M, Gonzalez-Bermejo J, Hart N, Lujan M, Nasilowski J, Nava S, Pepin JL, Pisani L, Storre JH, Wijkstra P, Tonia T, Boyd J, Scala R, Windisch W. European Respiratory Society guidelines on long-term home non-invasive ventilation for management of COPD. Eur Respir J. 2019 Sep 28;54(3):1901003. doi: 10.1183/13993003.01003-2019. PMID: 31467119.

The European Respiratory Society (ERS) created a task force to develop guidelines aimed at providing evidence-based recommendations on the use of long term home noninvasive ventilation (LTH-NIV) for patients with hypercapnic COPD. The task force consisted of clinical experts in the field of noninvasive ventilation as well as clinicians representing the ERS Assemblies of Respiratory Intensive Care, Sleep and Breathing Disorders, and Clinical Physiology. Additionally, methodologists with experience in evidence synthesis and guideline development using GRADE methodology were present on the taskforce as was a representative from the European Lung Foundation who reported on the patient perspectives gathered from a home mechanical ventilation survey. The taskforce generated four PICO (target population-intervention-comparator-outcome) questions to aid in the accomplishment of their goal. Based on those questions, the following recommendations were offered:

- The ERS task force suggested LTH-NIV be used for patients with chronic stable hypercapnic COPD (conditional recommendation, low certainty evidence).
- The ERS task force suggested LTH-NIV be used in patients with COPD following a life-threatening episode of acute hypercapnic respiratory failure requiring acute NIV, if hypercapnia persists following the episode (conditional recommendation, low certainty evidence).
- The ERS task force suggested titrating LTH-NIV to normalize or reduce PaCO2 levels in patients with COPD (conditional recommendation, very low certainty evidence).
- The ERS task force suggested using fixed pressure support mode as first-choice ventilator mode in patients with COPD using LTH-NIV (conditional recommendation, very low certainty evidence).

The task force highlighted the generalized uncertainty surrounding the evidence for these recommendations. Therefore, it stated that the recommendations would require consideration of individual preferences, resource considerations, technical expertise availability, and the clinical circumstances of the patient prior to implementation of their suggestions. In all, different choices are likely to be appropriate for different patients and the treatments prescribed should be tailored to individual circumstances, values and preferences.

The task force also discussed various issues other than the above, which they believed impacted the effectiveness of long-term noninvasive ventilation in COPD. Among these topics was the subject of adherence to therapy. After consideration of the available evidence, the task force stated that five hours of long term home noninvasive therapy per day would be a reasonable target, though it noted that if patients do not achieve this amount of treatment time, they may still receive clinicalbenefit. Moreover, the task force recommended that ventilators without a battery "…will be used when NIV is used for less time in each 24-hour period. If the patient uses it for a longer duration (approximately 12 h per day, depending on individual circumstances) a ventilator with internal battery should be considered."

The Canadian Thoracic Society Clinical Practice Guideline

Kaminska M, Rimmer KP, McKim DA, Nonoyama M, Giannouli E, Morrison DL, O'Connell C, Petrof BJ & Maltais F (2021): Long-term non-invasive ventilation in patients with chronic obstructive pulmonary disease (COPD): 2021 Canadian Thoracic Society Clinical Practice Guideline update, Canadian Journal of Respiratory, Critical Care, and Sleep Medicine, DOI: 10.1080/24745332.2021.1911218

The objective of the Canadian Thoracic Society Clinical Practice Guideline was to provide updated clinical recommendations regarding the use and optimization of long-term NIV in the treatment of patients with severe chronic hypercapnic respiratory failure of COPD (FEV1 < 50% predicted). The guideline was focused on two target groups: (1) individuals with severe COPD and hypercapnia who were stable and (2) individuals with COPD and persistent hypercapnia following a severe COPD exacerbation that required NIV in the acute setting. The guideline panel was comprised of seven adult respirologists, one physiatrist who specialized in neuro-rehabilitation and one respiratory therapist. Searches were conducted for English language RCTs published between June 1, 2010 through November, 2020. The topic of chronic hypercapnia in COPD and concomitant sleep apnea or obesity related hypoventilation was not considered. The Cochrane Risk of Bias Tool for RCTs was used to assess the risk of bias in individual studies. GRADE evidence profiles were developed to rate the certainty of evidence.

The Guidelines made the following recommendations:

- In patients with stable severe COPD and chronic hypercapnic respiratory failure ($PaCO_2 \geq 52$ mmHg), it was suggested that long-term NIV be used to improve survival (SOE: weak/conditional; low certainty).
- In patients with severe COPD on LTOT who remain significantly hypercapnic (persistent $PaCO_2 \geq 52$ mmHg) 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 $PaCO_2 \geq 52$ mmHg) 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).

The authors noted that this 2021 guideline update demonstrated a significant shift in the approach to long-term NIV in patients with COPD and chronic hypercapnic respiratory failure, moving from a previous 2011 recommendation of not using this treatment option in most circumstances to a favorable (though weak/conditional) recommendation for its use in particular contexts. Specifically, it is recommended that it is important to offer this therapy in line with patient preferences where long-term NIV will be utilized for more than five hours per day and in whom it is successful in reducing $PaCO_2$ and in controlling nocturnal hypoventilation. Further research was encouraged.

American Thoracic Society Clinical Practice Guideline

Macrea M, Oczkowski S, Rochwerg B, Branson RD, Celli B, Coleman JM 3rd, Hess DR, Knight SL, Ohar JA, Orr JE, Piper AJ, Punjabi NM, Rahangdale S, Wijkstra PJ, Yim-Yeh S, Drummond MB, Owens RL. 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. doi: 10.1164/rccm.202006-2382ST. PMID: 32795139; PMCID: PMC7427384.

These clinical practice guidelines regarding the use of NIV (bi-level positive airway pressure) were prepared on behalf of the American Thoracic Society Assembly on Sleep and Respiratory Neurobiology. The panel consisted of 12 physicians and 2 respiratory therapists with expertise in the field of domiciliary NIV and/or COPD. Also included on the panel were two clinician-methodologists with experience in evidence synthesis and guideline development using GRADE (Grading of Recommendations, Assessment, Development and Evaluation methodology). There was also

participation of patient partners to aid in question selection and outcome prioritization.

The panel prioritized 5 PICO (patients, intervention, comparator and outcome) questions for the guideline to address. Medical librarians and the two methodologists conducted searches for English language observational trials, RCTs and systematic reviews for each PICO question in various databases from inception to April 2019. The direction and strength of recommendations were decided by consensus.

For patients with chronic (FEV1/FVC < 0.70; resting PaCO2 > 45 mm Hg; not during exacerbation) hypercapnic respiratory failure due to chronic obstructive pulmonary disease,

1. The panel suggested the use of nocturnal NIV in addition to usual care for patients with chronic stable hypercapnic COPD (conditional recommendation, moderate certainty).

2. The panel suggested that patients with chronic stable hypercapnic COPD undergo screening for OSA before initiation of long-term NIV (conditional recommendation, very low certainty).

3. The panel suggested not using in-hospital initiation of long-term NIV during an episode of acute-on-chronic hypercapnic respiratory failure, favoring instead reassessment for NIV at 2-4 weeks after resolution (conditional recommendation, low certainty).

4. The panel suggested 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).

5. The panel suggested NIV with targeted normalization of PaCO2, in patients with hypercapnic COPD on long-term NIV (conditional recommendation, low certainty).

Despite these recommendations, the Panel noted that many issues surrounding the provision of NIV for patients with stable hypercapnic COPD remained to be considered. For example, the studies reviewed to support the recommendations excluded individuals with known obstructive sleep apnea and/or severe obesity. The studies also were found to frequently initiate NIV in the hospital as opposed to the home; an approach that may not mimic real world clinical practice. Additionally medical expertise in NIV may be lacking in certain areas of the country, thereby establishing conditions for potential healthcare disparities. These and other limitations of the available research suggested to the Panel that further research is needed to help determine the optimal management of those patients who might benefit from NIV.

Swiss Society of Pulmonology

Janssens JP, Michel F, Schwarz EI, Prella M, Bloch K, Adler D, Brill AK, Geenens A, Karrer W, Ogna A, Ott S, Rüdiger J, Schoch OD, Soler M, Strobel W, Uldry C, Gex G; on behalf of the Special Interest Group on Ventilation and Oxygen Therapy of the Swiss Society of Pneumology. Long-Term Mechanical Ventilation: Recommendations of the Swiss Society of Pulmonology. Respiration. 2020 Dec 10:1-36. doi: 10.1159/000510086. Epub ahead of print. PMID: 33302274.

The Swiss Society of Pulmonology (SSP) and the Swiss Society of Pediatric Pulmonology published recommendations on home mechanical ventilation. This narrative review included the most recent recommendations of the group based on an extensive review of the medical literature through PubMed over the past 10 years, of other national guidelines, and of the specifics of care for long-term HMV in Switzerland. The final text was discussed among the members of the Special Interest Group on HMV (SIG) to reach a consensus. The text focuses on HMV provided at home or in

long-term care institutions. In long-term NIV, bi-level positive pressure support ventilation in spontaneous/timed mode is noted to be the most commonly used mode in clinical practice. Therefore, the recommendations presented focus on this mode.

Based on the evidence and the recent guidelines published by the ERS task force on NIV in COPD, the SIG suggested the following recommendations (all conditional):

- Long-term NIV should be used in chronic stable hypercapnic patients (PaCO2 > 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 (PaCO2 > 7 kPa [52.5 mm Hg]) persists 2–4 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 2-4 weeks remains undetermined.
- When implementing NIV in COPD patients with chronic hypercapnic respiratory failure, settings should be adjusted to decrease PaCO2 below 6.5 kPa (50 mm Hg) or reduce PaCO2 levels by more than 20% of baseline level.
- When implementing NIV in COPD patients with chronic hypercapnic respiratory failure, fixed pressure support ventilation should be preferred to auto-titrating modes as first-choice mode.

CMS also considered the following professional society position statements for this proposed decision.

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) program

Global Initiative for Chronic Obstructive Lung Disease 2025 Report. Accessed December 18, 2024 at **https://goldcopd.org/wp-content/uploads/2024/11/GOLD-2025-Report-v1.0-15Nov2024_WMV.pdf**

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) program was begun in 1998 with the aim of producing recommendations for the management of COPD based on the best scientific evidence available. The GOLD Science Committee, an invited group of volunteers recognized as leaders in the field of COPD clinical practice and research, reviews published material regarding the prevention and management of COPD, in order to provide recommendations to diagnose, assess and treat the disease.

The 2025 GOLD Report comments that noninvasive ventilation is occasionally used in patients with stable very severe COPD. Whether to use NIPPV chronically at home to treat patients with acute on chronic respiratory failure after hospitalization is undetermined and may be influenced by persistent hypercapnia.

However, in patients with both COPD and obstructive sleep apnea, the Report states that there are clear benefits to the use of CPAP to improve both survival and the risk of hospital admissions.

Technical Expert Panel Report From the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society

Hill NS, Criner GJ, Branson RD, Celli BR, MacIntyre NR, Sergew A; ONMAP Technical Expert Panel. Optimal NIV Medicare Access Promotion: Patients With COPD: A Technical Expert Panel Report From the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society. Chest. 2021 Nov;160(5):e389-e397. doi: 10.1016/j.chest.2021.06.082. Epub 2021 Jul 30. PMID: 34339684; PMCID: PMC8628175.

The American College of Chest Physicians, the American Academy of Sleep Medicine, the American Association for Respiratory Care and the American Thoracic Society developed and published a Technical Expert Panel (TEP) report on recommendations to revise CMS policies regarding the delivery of NIV therapy to Medicare beneficiaries.

The following recommendations regarding coverage of BPAP devices and HMVs for those individuals with COPD were applicable to consideration in this NCA:

- Removal of the current requirement for a nocturnal oximetry study using either 2L/min nasal oxygen or the patient's usual FiO2 (whichever is higher) to qualify for a RAD.
- Removal of the requirement that patients start with a BPAP device without a backup rate before they are eligible for a BPAP device with backup rate.

For individuals with severe COPD, all of the following criteria need to be satisfied:

- Require an ABG while awake and receiving supplemental oxygen (if prescribed) displaying a PaCO2 ≥ 52 mm Hg for initiation of BPAP therapy.
- Require OSA and CPAP treatment to have been considered and ruled out prior to receipt of BPAP device (formal testing not required; this only requires clinical documentation).
- Consider the use of an HMV for patients with severe hypercapnic COPD who:
    - Require higher inspiratory pressures than those deliverable by E0471 [respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, e.g. nasal or facial mask (intermittent assist device with continuous positive airway pressure device)] or,
    - Require FiO2 higher than 40% or 5 L/min nasally or,
    - Require device support for 10 h per day or greater (i.e., daytime use) or,
    - Require both sophisticated alarms and accompanying internal battery (high-dependency patient) or,
    - Require mouthpiece ventilation during the day or ,
    - Demonstrate persistence of hypercapnia with PaCO2 ≥ 52 mm Hg despite adequate adherence to BPAP therapy.

It was also recommended that a second 90-day trial period be covered for those patients not meeting the current adherence requirements[2] for continued coverage who return at least twice to a treating physician and see benefit from continued use. Furthermore, it was recommended that rehospitalization would constitute criteria for a new HMV initiation trial even in those previously failing to meet adherence criteria.

The TEP also concluded that the expertise of experienced clinicians (e.g. respiratory therapists) to provide home support for individuals receiving home NIV is critical to patient care whether that patient is using a RAD or HMV in the home.

VIII. Public Comment

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination.

CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum. Public comments that contain personal health information will be redacted or will not be made available to the public on the CMS website. All comments that are submitted without personal health information may be viewed in their entirety by using the following link https://www.cms.gov/medicare-coverage-database/view/ncacal-public-

comments.aspx?ncaid=315&ncacaldoctype=all&status=all&sortBy=status&bc=17.

Initial Comment Period: 9/11/2024-10/11/2024

During the initial 30-day public comment period following the release of the tracking sheet, CMS received 72 comments. The majority of commenters were supportive of an NCD for the use of noninvasive respiratory assist devices (RADs) and home mechanical ventilators (HMVs) for the treatment of chronic respiratory failure (CRF) consequent to COPD. Six comments requested the NCD process be paused until the durable medical equipment (DME) Medicare Administrative Contractors (MACs) complete their review of the current LCD for respiratory assist devices.

The majority of comments were provided by physicians. Other comments were provided by respiratory therapists, DME providers, device manufacturers, professors, and healthcare companies. Eight comments were provided by national associations/professional organizations/coalitions including American Association for Respiratory Care (AARC), American Academy of Sleep Medicine (AASM), American Association for Homecare (AAHomecare), Advanced Medical Technology Association (AdvaMed), American Thoracic Society (ATS), American College of Chest Physicians (CHEST), Council for Quality Respiratory Care (CCRQ), and the COPD Foundation. One comment was provided by the requestor, the Optimal Noninvasive Ventilation Medicare Access Promotion Technical Expert Panel (TEP) consisting of representatives from the American College of Chest Physicians, the American Academy of Sleep Medicine, the American Association for Respiratory Care, and the American Thoracic Society.

Numerous commenters provided references for our deliberation of this NCA. We very much appreciate this information. All such references were assessed for inclusion in our evidence review.

IX. CMS Analysis

NCDs are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally by Medicare (§1869(f)(1)(B) of the Act). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A) of the Act).

When making NCDs, we evaluate the evidence related to our analytic questions based on the quality, strength and totality of evidence presented in the reviewed literature. As part of this evaluation, it is important to consider whether the evidence is relevant to the Medicare beneficiary population. In determining the generalizability of the results of the body of evidence to the Medicare population, we consider, at minimum, the age, race, and gender of the study participants.

This section provides an analysis of the evidence we considered during our review. The evidence includes the pertinent published medical literature and guidelines pertaining to the use of NIV for patients with chronic hypercapnic respiratory failure consequent to COPD. For details of each of the clinical trials, see the Evidence Table in Section VII above.

In this analysis, we addressed the question(s) below:

1. In the patient with chronic hypercapnic respiratory failure consequent to COPD, is the evidence sufficient to provide coverage of a RAD with backup rate feature for initial NIV support in the home in the patient who

either exhibits stable COPD or is status post a recent exacerbation of COPD?
2. In the patient with chronic hypercapnic respiratory failure consequent to COPD, is the evidence sufficient to determine if there are any conditions under which coverage of an HMV is reasonable and necessary?
3. In the patient with chronic hypercapnic respiratory failure consequent to COPD, is the evidence sufficient to establish a 180-day trial period to determine if the use of home NIPPV delivered either from a bi-level respiratory assist device or a HMV, is reasonable and necessary?

In evaluating the evidence that pertains to our key questions, we are placing high importance on the impact of the patient centered outcomes of mortality and the need for repeat hospitalizations in our beneficiary population that experiences COPD. We believe strongly that therapeutic interventions should better these characteristics of the disease while at the same time improving, or at least not worsening, the impact of the disease on the patient's perceived quality of life.

- **In the patient with chronic hypercapnic respiratory failure consequent to COPD, is the evidence sufficient to provide coverage of a RAD with backup rate feature for initial NIV support in the home in the patient who either exhibits stable COPD or is status post a recent exacerbation of COPD?**

NIV has been validated as a useful treatment of hospitalized patients with acute hypercapnic respiratory failure consequent to COPD. In the inpatient environment, the treatment of acute hypercapnic respiratory failure with NIV is known to decrease length of stay, as well as reduce mortality and the risk of intubation (Gantzhorn, Prior & Hilberg, 2019; Raveling et al., 2021). However, the evidence describing the benefit of home NIV in patients with chronic hypercapnia secondary to COPD has not been as well established (Suh, Murphy & Hart, 2019; Macrea & Coleman, 2022).

That long term home administration of NIV has not been considered a standard of care may be due to heterogeneity of the very studies performed to examine the treatment. For example, in a recent Cochrane review (Raveling et al., 2021), trials of individuals with stable COPD spanning from 1991 to 2019, included investigations of NIV (bi-level pressure support) applied with backup rates, without backup rates, with unspecified backup rates or with an unspecified ventilation mode. In another grouping of studies, the comparators of chronic NIV treatment in COPD patients were standard treatment or sham treatment in the form of CPAP, with NIV being applied in some investigations in addition to pulmonary rehabilitation or an exercise training program with the control population receiving only the physical therapeutic program. We believe that a collection of studies with such fundamental and varied differences in management techniques may possess too many variables to determine the usefulness (or not) of home NIV in patients with severe COPD.

Nevertheless, in a previous Cochrane review which investigated the chronic use of NIV in patients with stable COPD, it was noted that while the therapeutic use of this treatment did not provide significant benefits in terms of gas exchange, exercise capacity, lung function or quality of life, there was a subgroup of COPD patients with severe hypercapnia who seemed likely to benefit from the treatment, especially when it was provided with high inspiratory pressures and when NIV was used for more than five hours per day (Raveling, et al., 2021).

The concern that low inspiratory pressures may not improve the blood gases or survival of patients with stable COPD had been previously considered by various investigators, including Windisch, Kostić, Dreher, Virchow & Sorichter (2005). These authors noted indirect evidence existed to support the hypothesis that more aggressive ventilation aimed at maximally decreasing PaCO2 could provide beneficial effects for patients with stable hypercapnia due to COPD. Therefore, they performed a retrospective analysis of a medical database of stable COPD patients who presented with typical symptoms of hypercapnic respiratory failure (e.g. fatigue, dyspnea, morning headache) and who received pressure limited NPPV therapy in the assist/control mode by nasal mask in the hospital setting. NPPV was titrated to achieve passive ventilation with a maximal decrease in PaCO2 by stepwise increases in inspiratory

pressures. Supplemental oxygen was also added to the NPPV in order to maintain an arterial oxygen saturation greater than 95%. Patients were discharged from the hospital when a maximum reduction in PaCO2 was achieved and maintained for two days with inspiratory pressures set to the maximum tolerated by each individual. Patients predominantly used their NPPV at night but could use it up to four hours during the daytime as needed to control hypercapnia and symptoms.

The authors found that NPPV used in the assist /controlled mode[3], along with supplemental O2 using a high mean inspiratory pressure of 27.7 ± 5.9 cm H20 (range 17- 40 cm H2O) could be well tolerated over long periods of time by patients with stable hypercapnic COPD (mean age 63.4±9.7 years) at a mean respiratory rate of 20.8 ±2.5 breaths per minute (range 14-24 breaths per minute). Moreover, in the group of patients tested, daytime PaCO2 during spontaneous breathing significantly decreased (6.9±8.0 mm Hg; 95% CI: -9.9 to -3.9) from 53.3±4.8 to 46.4 ± 7.0 mm Hg ($p < 0.001$) after 2 months. The 2-year survival rate was 86 %.

The ventilator parameters as exemplified above described more intense settings than did those of many studies that used lower levels of inspiratory positive airway pressures (IPAP) ranging from 12 to 18 cm H2O. These higher settings were therefore designated high intensity NPPV and signaled the use of high inspiratory pressures with a high backup rate (slightly above the natural breathing frequency, typically 14-18 breaths per minute) targeted at producing significant reductions in PaCO2 (Carlucci, Patout & Winck, 2023; Kaminska et al., 2021; Suh, Murphy & Hart, 2022; Windisch, Haenel, Storre & Dreher, 2009). Researchers believed that among the next steps for study of this topic was the verification through prospective randomized controlled trials that in individuals with chronic hypercapnic respiratory failure as a result of COPD, high intensity NPPV could improve clinical outcomes of lung function such as survival and reduction of exacerbation/hospitalization rates (Windisch et al., 2005; Windisch et al., 2009).

There are three trials meeting our inclusion criteria that address whether high intensity NPPV improves survival and/or reduces hospitalization of patients with hypercapnic COPD. (The fourth study noted in the Tables above (Clini, et al., 2002) did not provide high intensity NIV to its patient sample (Clini et al., 2002; Coleman, Wolfe & Kalhan, 2019) and therefore will not be discussed.) Though the details of these studies are summarized in Tables 1 and 2 above, for purposes of our analytic discussion, we highlight several aspects of these investigations emphasizing those points which allow us to associate the use of high intensity ventilation with a backup rate to our analytic questions and outcomes of interest for both patients experiencing stable COPD and those with recent exacerbations.

Kohnlein et al., 2014: In this trial, 195 patients with stable GOLD Stage IV COPD, PaCO2 of 51.9 mm Hg or higher (mean PaCO2 approximately 58 mm Hg) and a pH greater than 7.35, were randomized into two groups: those who were treated with standard therapy and those who were treated with standard therapy as well as NPPV targeted to reduce baseline PaCO2 to either achieve a value lower than approximately 48 mmHg or to reduce the baseline value by 20% or more. As per the authors, these individuals had no acute exacerbation during the four week run in period before randomization, defined as an increase in or new onset of, more than one respiratory symptom (cough, sputum production, sputum purulence, wheezing, or dyspnea) lasting 2 days or more. The authors also required their patient population to have had no change of pharmacological treatment in the preceding four weeks. Potential patients were ineligible if they demonstrated a BMI ≥ 35 kg/m^2. Both groups were admitted to the hospital for initiation of treatment and for regularly scheduled follow up after randomization. All ventilators were set in pressure support mode; ventilation with high backup rates was preferred to achieve controlled ventilation, but assisted ventilation was also allowed if patients did not accept high backup rates. The mean inspiratory pressure was 21.6 (4.7) cm H2O, the mean expiratory pressure was 4.8(1.6) cm H2O and the mean backup rate was 16.1 (3.6) breaths per minute (range 2-24), reflective of a high intensity strategy. Mean NPPV use was 5.9 (3.1) hours per day. Long term oxygen therapy was allowed.

The primary outcome of this study was one-year all-cause mortality. The trial demonstrated a significant decrease in mortality when NPPV was added to usual treatment. NPPV treatment was associated with a one-year mortality of

12% (12/102 patients) in the intervention group as compared with 33% (31/93 patients) in the group who did not receive this treatment. There was also an effect on PaCO2, as at the end of one year, the mean value in the intervention group was (approximately) 48.75 mm Hg versus (approximately) 55.50 mmHg in the control group. Changes in the disease specific quality of life summary scores of both the St George's Respiratory Questionnaire (SGRQ) and the Severe Respiratory Insufficiency Questionnaire (SRI) improved in favor of the NPPV group.

(We do note that the trial by Kohnlein and colleagues (2014) was terminated prior to attaining the full sample population. However, this was done as a result both of a change in national guidelines for the provision of NIV as well as the unexpectedly high mortality rate of the control group [Suh, Murphy & Hart, 2022]).

Struik et al., 2014: In the RESCUE study (Struik et al., 2014), 201 individuals treated as inpatients for acute hypercapnic respiratory failure secondary to COPD (GOLD stage 3 and 4), with ventilatory support (invasive or non-invasive) who exhibited prolonged hypercapnia (> 45 mm Hg for greater than 48 hours after termination of ventilatory support) were randomized to nocturnal NIV (bi-level spontaneous/timed mode; n=101) or standard treatment (n=100). Mean baseline PaCO2 value was approximately 58.5 mm Hg for all patients. Patients randomized for NIV were discharged from the hospital with a mean IPAP of 19.2 ±3.4 and EPAP of 4.8 ±1.0 cm H2O and a mean respiratory rate of 15 ±3 breaths/minute. Sixty-eight per cent of ventilated patients received nighttime oxygen. After one year, those who remained in the study in the intervention group (54/101), were ventilated with a mean IPAP of 21.0 ±3.4 and an EPAP of 5.2±1.2 cm H2O. Mean duration of NIV use per night until last follow up or death was 6.3 ±.4 hours per night in the total group and 6.9 ±2.1 hours per night in the completers. At one year, despite an improvement in day and night time PaCO2, there was no improvement in time to readmission for respiratory causes or death (primary endpoint) in those who received nocturnal NIV versus those who did not.

Murphy et al., 2017: The Home Mechanical Ventilation versus Home Oxygen Therapy in COPD study (HOT-HMV) included individuals who had been hospitalized with an acute decompensated exacerbation of COPD requiring NIV and were screened for eligibility at least 2 weeks after resolution of decompensated acidosis and within 4 weeks of attaining clinical stability. Among other criteria, the patients were required to have persistent hypercapnia with PaCO2 > 53 mmHg, pH greater than 7.3 breathing room air, hypoxemia, FEV1 < 50% predicted and FEV1/FVC < 60%. Exclusion criteria included a body mass index > 35 kg/m ^{2} or clinically significant obstructive sleep apnea syndrome.

Fifty-nine patients were randomized to home oxygen alone and 57 patients to home oxygen and bi-level positive airway pressure. The median ventilator settings at hospital discharge were an IPAP of 24 cm H20 (IQR 22-26 cm H2O), EPAP of 4 cm H20 (IQR 4-5 cm H2O), and a backup rate of 14 breaths per minute (IQR 14-16 breaths/minute). Ventilator use at 6 weeks was 4.7 hours per night (IQR, 2.5-5.6 hours per night), which increased during the trial to 7.6 hours per night (IQR, 3.6-8.4 hours per night) at 12 months. Home oxygen therapy was provided as needed in order to increase the PaO2 level to greater than 60 mm Hg without producing decompensated respiratory failure.

The primary outcome was time to readmission or death within 12 months after randomization. Sixty-four patients (28 in the home oxygen therapy alone group and 36 in the home oxygen therapy plus home NIV group) completed the 12-month study period. There was a statistically significant between-group difference in daytime PaCO2 at 6 weeks and 3 months favoring the home oxygen therapy plus home noninvasive ventilation group, but not at 12 months. Median time to hospital readmission or death was 4.3 months (IQR, 1.3-13.8 months) in the NIV group versus 1.4 months (IQR, 0.5-3.9 months) in the home oxygen group alone.; The 12-month risk of readmission was 63.4% in the NIV group versus 80.4% in the home oxygen group, yielding an absolute risk reduction of 17% (95% CI: 0.1%-34.0%). Twelve-month mortality was not significantly different between groups, but there was a reduction in the COPD exacerbation rate in the NIV group (median 3.8 exacerbations per year; IQR, 1.7-6.0) compared with home oxygen alone (median 5.1 exacerbations per year; IQR 1.0-9.2). There were also no significant differences in health-related quality of life as measured by the St. George's Respiratory Questionnaire or the Severe Respiratory

Insufficiency Questionnaire mean scores at 12 months.

The studies performed by Kohnlein et al., 2014, Struik et al., 2014 and Murphy et al., 2017 noted above, utilized high inspiratory pressures and backup rates of respiration and are therefore classified as providing high intensity NIV. In the studies by Kohnlein et al., 2014 and Murphy et al., 2017, the application of home NIV led to improved survival or readmission rates. In contrast, though the RESCUE study by Struik et al., 2014, provided NIV at similar pressures and respiratory rates as in Kohnlein et al, 2014, it did not demonstrate improvement in mortality or readmission in patients with severe COPD who used NIV at home. The benefits found in the Kohnlein et al., 2014 and Murphy et al., 2017 studies contrasting with the lack of same in the RESCUE trial indicate that the timing of long-term high intensity NIV application may be crucial to its success. For those who are status post an acute exacerbation of disease, it appears to be prudent to reassess need for home high intensity NIV two to four weeks after resolution of the illness in order to show benefit of NIV compared with controls. More generally, it seems that that NIV may be best applied in the patient with persistent hypercapnia, as opposed to the individual who may still be recovering from an acute exacerbation (Coleman, Wolfe and Kalhan, 2019).

It is also important to note that in the Kohnlein et al., 2014 study, the St. George Respiratory Questionnaire summary scale score as well as the Severe Respiratory Insufficiency Questionnaire summary scale score improved more with NIV than with LTOT alone. In the Murphy et al., 2017 study at the end of 12 months, there were no significant differences demonstrated in the Severe Respiratory Insufficiency Questionnaire or the St. George's Respiratory Questionnaire. These findings provide evidence that appropriately applied high IPAP and high respiratory rates can improve outcomes in the patient with chronic COPD, without jeopardizing quality of life and adding to the patient's burden of disease.

Admittedly, this collection of literature has some limitations that are worthy of mention. Firstly, the Kohnlein et al., 2014 and Murphy et al., 2017 studies were conducted in Europe, and their protocols called for either hospital admissions every 3 months to ensure optimized medical and NIPPV treatment or NIV training from skilled teams at home ventilation centers in the United Kingdom. These conditions appear unique to European countries and are likely not generalizable to the US Medicare population. It is certainly possible that the extra services afforded to patients undergoing NIV in countries outside the US may have influenced the results of these investigations.

Important to the consideration of this NCA, we are also aware that there is some controversy as to whether or not the backup rates that accompany the high-intensity noninvasive ventilation approach play an important role in the management of hypercapnic respiratory failure in COPD patients or if it is only the high-pressure settings that are needed for the therapeutic management of the condition. We agree with the opinions expressed in national guidelines that the available studies on this topic are insufficient to recommend the use of high-pressure NIV as opposed to high intensity NIV, encouraging further research on the topic (Kaminska et al., 2021; Ergan et al., 2019).

There is also some concern that high intensity NIV as compared to low intensity NIV may cause a reduced cardiac output, particularly in those individuals with pre-existing severe cardiovascular disease. Data is also conflicting in this area and varying effects on cardiac output may depend on individual patient characteristics and device settings (Lukácsovits, Carlucci, Hill et al., 2012; Duiverman, Maagh, Magnet et al., 2017). Though this does not appear to cause a blanket reason to withhold high intensity NIV from appropriate patients with COPD, it does inform treating practitioners regarding potential adverse effects of the use of this therapy in patients with co-morbid heart conditions and the need to follow the heart function of these patients carefully (Duiverman et al., 2017).

Other potential adverse effects of NIV cited in the literature are dry throat, facial pain, fragmented sleep, impaired nasal breathing, abdominal bloating, flatulence, eye irritation, sleep impairment, nose bleeds, nausea, vomiting and facial pressure wounds (Windisch, Geiseler, Simon, Walterspacher & Dreher, 2018). However, in the Kohnlein et al., 2014 study, the only side effect of the therapy reported was that of facial skin rashes which occurred in 14% of the

intervention population (14 of 102 patients). This side effect was managed in all affected patients by changing the type of the mask worn. The Murphy et al., 2017 study did not report adverse events of NIV. The authors of the RESCUE trial stated they did not find a difference in adverse events between groups.

Another area of controversy in this field of long-term home NIV for COPD is the setting in which this therapy is initiated. Though some clinicians believe it best to admit their patients to hospitals or sleep laboratories to titrate NIV settings in order to initiate this therapy for their patients with chronic stable COPD, the ATS suggested that an in-laboratory overnight PSG to titrate NIV in patients with chronic stable hypercapnic need not be used in those who are initiating NIV. However, there may be special circumstances in which in-laboratory overnight testing is warranted as described below (Macrea et al., 2020). Therefore, we believe it best to leave this decision to the discretion of the treating practitioner who will know the availability and quality of the local resources as well as the unique needs and potential complexities of the individual patient.

An important co-morbidity associated with COPD is obstructive sleep apnea (OSA), a disease characterized by repetitive closings of the upper airways during sleep (Marin, Soriano, Carrizo, Boldova & Celli, 2010). The prevalence of OSA in those with severe COPD (COPD-OSA overlap syndrome) is unknown (Macrea & Coleman, 2022), though moderate or severe sleep apnea has been generally diagnosed in 30–50% of COPD patients (Czerwaty, Dżaman, Sobczyk & Sikorska, 2023). This is an important consideration; the ATS has noted several studies demonstrating that those individuals with COPD and OSA have more profound nocturnal oxygen desaturations and sleep disturbances compared to individuals displaying either disease alone (Macrea et al., 2020). Moreover, with the co-existence of the two diseases, individuals may also have increased risk of hospitalization and death due to COPD exacerbation. (Kuklisova et al., 2017).

Neither the Murphy et al., 2017 nor the Kohnlein et al., 2014 study specifically examined how the overlap condition would affect the outcomes of NIV used for COPD. Currently practitioners may use CPAP or BPAP to treat their hypercapnic patients with overlap syndrome (Kuklisova et al., 2017, Nowalk, Neborak & Mokhlesi, 2022: Orr et al,2020; Suh, Murphy & Hart, 2022; Zheng et al., 2022), although for those with chronic respiratory failure titration with in-laboratory overnight testing may be useful to set EPAP parameters (Macrea et al., 2020; Macrea & Coleman, 2022). A concern of this approach though is that the high expiratory positive airway pressure (EPAP) that may be required to overcome upper airway obstruction in these individuals may lead to worsening lung hyperinflation which has been reported to be correlated with poor outcomes (Suh et al., 2022). We believe further study in this area is needed. In the meantime, whereas CPAP alone may be the therapeutic device of choice in those whose OSA is the major contributor to their chronic respiratory failure, we believe that those individuals with overlap syndrome whose hypercapnic state is judged to be mostly due to their COPD, may benefit from the use of bi-level respiratory assist devices.

Despite the questions still to be answered in this research field, overall, we find it difficult to ignore the significant outcomes in survival/mortality, hospital readmission rates and reduction in the exacerbation rate that have been achieved for COPD patients with severe disease using NIV at high inspiratory pressures with a high backup rate targeted at producing significant reductions in PaCO2, as exhibited by the studies of Kohnlein et al., 2014 and Murphy et al., 2017. We also note that avoiding exacerbations and hospitalization due to exacerbations has been reported as the outcomes that patients with COPD consider to be the most important in this disease (Hurst, Skolnikb, Hansen et al., 2020).

Therefore, despite the limitations of the evidence, we are proposing coverage of nocturnal bi-level respiratory assist devices with backup rate capability as initial therapy in the treatment of severe COPD. We believe that an essential criterion for initiation of a RAD with backup rate feature should be a daytime PaCO2 measurement (≥ 52mmHg by arterial blood gas), as was done in both the Kohnlein et al., 2014 and Murphy et al., 2017 studies. However, though improvement in PaCO2 is a common endpoint used in studies of patients with chronic hypercapnic respiratory failure, it remains unclear if the benefit of PAP is mediated directly through PaCO2 reduction or whether PaCO2 is a marker

for other PAP benefits such as ventilation/perfusion matching, respiratory muscle rest during sleep, improving airway obstruction, improvement in hypoxemia (Nowalk et al., 2022). Therefore, we believe it appropriate to propose to characterize the successful use of bi-level respiratory assist devices with backup rate capability as achieving a normalization of PaCO2, a 20% reduction in baseline PaCO2, and /or improved patient symptoms. Furthermore, as we also believe that the key to the potential success of this equipment are the patients selected for its use, we are additionally proposing that bi-level respiratory assist devices with backup rate capacity be reserved for those individuals with chronic stable hypercapnic COPD or for those patients who have been hospitalized with an exacerbation of COPD and remain hypercapnic for at least 2 weeks post discharge.

We do not, however, believe that high PaCO2 levels must occur in the wake of low sleep oximetry values in order to obtain a RAD with backup for a patient with severe COPD. As reported in a poster presentation in 2016, six hospitalized GOLD stage 3 and 4 clinically stable individuals who used nasal oxygen (1-4 L), whose baseline resting PaCO2 ≥ 52 mm Hg and who were nearing the end of a COPD exacerbation, were studied for 12 hours overnight off NIPPV. None of the recorded oximetry readings fell below 90% for any patient during the study period, yet median PvCO2 values increased overnight by 6.65±5.2 mmHg despite subjects spending 46% of the study time awake. Even though the study was small, it does illustrate that nocturnal venous hypercapnia in clinically stable COPD patients nearing the end of an exacerbation hospitalization can occur in the absence of significant hypoxemia (Kim, Marchetti & Criner; 2016).

More significantly perhaps, is that the literature has reported there are differences in the accuracy of the pulse oximeter readings when comparing the information obtained from these devices between persons who identified their race as Black or White. Though many of the individuals who identified themselves as Black did demonstrate accurate pulse oximeter values, their risk of experiencing occult hypoxemia (defined as an arterial oxygen saturation of <88% determined by arterial blood gas studies despite an oxygen saturation of 92 to 96% on pulse oximetry) was reported to be nearly three times that of individuals who designated themselves as White (Sjoding, 2020; CAG-00296R2, 2021). Such overestimation of oxygen saturation can foster inappropriate decision-making in the consideration of device needs for the COPD patient. Thus, we do not believe there should be a requirement for sleep oximetry testing in order to receive a RAD.

Additionally, given the uncertain nature of the optimum PAP devices/parameters that might be used for the treatment of COPD-OSA overlap syndrome, we believe that the choice between CPAP, low or high-intensity NIV to treat the combination of COPD and OSA depends on the individual characteristics of the patient's disease. Therefore, if sleep apnea is not the predominant cause of the hypercapnia in those individuals with overlap syndrome, it can be reasonable to consider treatment with NIV, depending on a patient's individual clinical characteristics.

- **In the patient with chronic hypercapnic respiratory failure consequent to COPD, is the evidence sufficient to determine if there are any conditions under which coverage of an HMV is reasonable and necessary?**

In developing this proposed NCA for RADs with backup rate functionality, we acknowledge that there are constraints to this equipment that may limit its capabilities. As a result, there may be circumstances when NIV may be best delivered through an HMV to patients with COPD who manifest particular characteristics. To our knowledge, there is no literature that collectively addresses this topic in a rigorous manner; therefore, below we will describe several scenarios that the requestors of this NCA have highlighted for us.

As has been described in this NCA, bi-level respiratory assist devices for the treatment of hypercapnic COPD are not meant for continuous use. In the vast majority of cases, these devices are used only during the night with nasal or oronasal interfaces to allow for reduction of the symptoms and adverse events associated with hypercapnia. However, in some individuals, NIPPV use may extend into daytime hours. If this is the case, the use of facial masks

during daylight hours impedes eating and drinking as well as social interaction. The prolonged use of these interfaces may also promote the formation of facial pressure sores (Pinto, 2017).

For those individuals who require the extended use of ventilatory support from nighttime into daylight hours to correct hypercapnia that persists despite optimized nocturnal NIV, mouthpiece ventilation (MPV) is an option to be considered. MPV is an on demand or intermittent type of ventilation where the patient initiates a device supported breath as s/he requires. It is not available on bi-level respiratory assist devices, but can be used with ventilators (Singh & Cao, 2020; Hansen-Flaschen & Ackrivo, 2023). In the home, MPV is usually performed via an HMV in the volume-assisted/controlled mode. Pressure modes are not usually utilized because of the high air flow that the devices continue to deliver when the patient is disconnected from circuit. Volume-cycled modes allow the patient to choose at every inspiration the amount of air which s/he wants to inhale, adjusting the seal with the lips on the mouthpiece (Pinto, 2017).

Though there are limitations to the use of MPVs, used with certain ventilators, inspiratory effort is not required to initiate this mode of breathing; instead, the patient can receive a breath through contact of the device tip with his/her lip, check or tongue or by placing their lips around the mouthpiece. In between breaths, appropriate device adjustments can reduce air flow to imperceptible rates. Users can take one breath every few minutes or continuously as desired. (Hansen-Flaschen & Ackrivo, 2023).

MPV has been reported to improve hypercapnia in patients with respiratory failure, in particular those with neuromuscular disease (Singh & Co, 2020). We could find no literature to describe the use of MPV in the home of the patient with hypercapnic COPD, though the interface has been used to treat COPD in hospitalized patients with acute exacerbations of COPD. In the inpatient setting, at least in the short term, symptoms or blood gases mostly improved (Glerant JC, Rose D, Oltean V et al., 2007; Nicolini A, Santo M, Ferrari-Bravo M & Barlascini, 2014; Annunziata, Lanza, Scotto Di Frega et al., 2018). Therefore, in the patient who requires daytime usage of respiratory assistance (in addition to nocturnal use), it may be reasonable and necessary to use MPV on an accommodating HMV.

For those individuals who require ventilatory support more than eight hours per 24 hour period, it may also be a pragmatic option to offer a nasal mask for use during daytime hours and a face mask (e.g. oronasal mask) for sleep. This may provide the patient with the ability to speak and eat while awake.

A differential feature between bi-level respiratory assist devices and ventilators is that the former have limited pressure capabilities; a characteristic that becomes important in the mechanism of patient ventilation. Provided the patient's respiratory muscles are relaxed, as they generally will be in long-term ventilator users utilizing controlled modes of NIV, the tidal volume achieved (the amount of air that is brought into and out of the lungs with every breath, a key determinant of the quantity of oxygen and carbon dioxide in the blood) will depend upon the difference between IPAP and EPAP (known as the pressure support). When ventilation during NIV is found to be inadequate, such as when there is persistent elevation of daytime $PaCO_2$, clinicians will frequently increase IPAP in order to augment tidal volume during each breath (Kinnear, Watson, Smith et al., 2017). The maximum IPAP that can be generated by a bi-level respiratory assist device is usually between 25-30 cm H_2O, while that of a traditional HMV may be up to 50-60 cm H_2O (Hansen-Flaschen & Ackrivo, 2023). In some individuals, for example those who may be obese, it may not be possible to generate an IPAP large enough through the use of a bi-level respiratory assist device to sufficiently improve the patient's ventilatory status; consequently, an HMV may be reasonable and necessary.

When supplemental oxygen is required by an individual who is hypoxemic and using a bi-level device, special ports can be attached to the bi-level respiratory assist device in order to deliver oxygen to the patient. However, the fraction of inspired oxygen (FiO_2), the resultant concentration of oxygen in the gas mixture, is not able to be easily

predicted in these circumstances. FiO2 during NIV can be affected by many factors including the location of the port through which the oxygen is bled into the system, the pressure settings being used, the amount of oxygen flow that is being entrained in the system, the site of the leak port and the impact of the leaks that may be caused either by the mask-face interface and/or from the mouth itself if a nasal mask is used. Therefore, when precise oxygen delivery is required, it may be reasonable to use a ventilator that has the ability to accurately mix the gases together in order to get a predictable concentration of oxygen (Scala & Naldi, 2008; Schwartz, Kacmarek & Hess, 2004). Additionally, though no substantial evidence can be found to support a FiO2 threshold, subject matter experts consulted by CMS have suggested that when severe hypoxemia is present defined by a supplemental oxygen requirement of greater than 4 liters per minute (FiO2 36%), it would be prudent that the amount of oxygen required be ensured through the use of an HMV.

As previously noted, HMVs typically have additional monitoring, safety, alarm, and backup power features (batteries), not possessed by a RAD. As such, we believe this equipment may be beneficial for those patients with severe COPD for whom loss of ventilatory support would, within minutes to hours, cause a life-threatening condition (e.g. those individuals with comorbid neuromuscular disease or diaphragmatic paralysis).

Based on the above discussion, and with the knowledge that the external Technology Assessment did not find any studies that compared the initiation criteria among different ventilatory devices (HMV vs. BPAP vs. CPAP) we do not believe that there is sufficient information to propose a policy that would definitively describe the difference between all patients with CRF and hypercapnia who have need for an HMV rather than a RAD in all situations. However, we do believe there are specific medical situations that may influence the choice between these two devices and are amenable to policy. Therefore, based on the evidence above, we propose to cover an HMV when a beneficiary requires a FiO2 ≥ 36%, when ventilatory support is required beyond nocturnal hours to reduce hypercapnia (and a MPV or an additional mask may be needed) and when the parameters of a RAD are not sufficient to accommodate the use of high intensity NIV (e.g. the patient requires IPAP > 30 cm H2O). Due to the alarms and internal battery of an HMV, we also propose to cover the use of this device, if the unrecognized loss of ventilatory support in the home could cause a threat to the life of a beneficiary.

Moreover, we believe that there exist some situations, driven more by clinical experience than literature, where it is medically appropriate for a patient to have access to either a RAD or home mechanical ventilator (depending on the beneficiary's individualized needs) at the time of hospital discharge. Based on the definitions of treatment success and failure posed by Mosher et al. (2022), we consider it to be clinically appropriate for a hospitalized patient to use these devices at home immediately after hospital discharge if the individual has experienced an acute exacerbation of COPD and cannot be 'liberated' from respiratory support as an inpatient without the demonstrated threat of serious consequence in the short term, such as the worsening of hypercapnia, the need for the use of invasive ventilatory assistance or death. Therefore, we propose to allow use of a RAD or an HMV when the beneficiary requires continuation of device usage to avoid rapidly developing signs and symptoms of severe chronic respiratory failure upon hospital discharge after the exacerbation of COPD.

However, we also believe that there are circumstances where a patient's need for an HMV, versus a RAD, may be less defined than can be described by specific policy. In such cases where we have not proposed coverage or non-coverage in this NCD, we intend to allow the DME MACs the discretion to cover ventilatory support equipment, including HMVs, based on the individual characteristics of the patient and their medical needs. The MACs are structured to be able to take into account individualized patient factors in the treatment of medical conditions.

3. **In the patient with chronic hypercapnic respiratory failure consequent to COPD, is the evidence sufficient to establish a 180-day trial period to determine if the use of home NIPPV delivered either from a bi-level respiratory assist device or a HMV, is reasonable and necessary?**

To our knowledge there are no RCTs that study the period of time needed to best allow COPD patients in need of NIV to adhere to the equipment and mode that their physician recommends in order to decrease PaCO2 and/or related symptoms. However, in the Kohnlein et al., 2014 study, patients in the intervention group were admitted to the hospital for a mean of 5.6 ±1.1 days in order to initiate their NIV therapy. In the intervention group, patients were advised to use NPPV for at least 6 h per day, preferably during sleep, but usage during daytime was also accepted. Over the course of the experimental year, at least one measure of exact ventilator usage was available in 122 3-months follow-up periods in a subset of 48 out of 102 patients (47%) of whom 65% (52.5% of periods) exceeded the prescribed usage time of more than 6 hours per day. Usage time was less than 3 hours in only 18.8% of patients (23.8% of periods). Mean NPPV usage was 5.9 ± 3.1 hours per day. In the one-year observation period, a total of nine patients discontinued NPPV. Three patients discontinued NPPV directly after initiation (after 1, 1, and 3 days). In the first 90 days a total of 4 patients discontinued NPPV; in the first 180 days a total of 5 patients discontinued NPPV (Kohnlein et al., 2014 and Supplementary appendix).

In the Murphy et al., 2017 trial, acclimatization to the use of high intensity NIV took 5-6 days (Coleman et al., 2019). By the end of 12 months, 5 patients had withdrawn (16 died). Ventilator use at 6 weeks for those who remained in the trial was 4.7 hours per night (IQR, 2.5-5.6 hours per night), which increased during the trial to 7.6 hours per night (IQR, 3.6-8.4 hours per night) at 12 months. (Murphy et al., 2017, Supplementary Online Content).

The evidence reviewed demonstrates that the COPD patients who participated in these European studies were introduced and acclimatized to their NIPPV in a matter of days. We understand that this occurred in highly supportive facility environments which are unlikely to be reproduced in the United States. Specifically, in the case of Medicare patients, though initiation of the device may take place in home or in facility depending on the judgement of the treating physician and the resources available, we expect the full adherence to the nightly use of NIPPV will most likely occur over a prolonged period of time while at home. Therefore, we believe it prudent to allow several months to accomplish this therapeutic task. We also note that the Kohnlein et al., 2014 and Murphy et al., 2017 (2017) studies as well as two evidence-based guidelines (Ergan et al., 2019; Kaminska et al., 2021) suggest that usage at least five hours per day will most likely provide the clinical benefits of delayed time to readmission or improvement of survival in those patients who utilize NIPPV.

At the time of the writing of this NCA, the evaluation of a Medicare beneficiary with COPD to continue the use of a RAD (with or without a backup rate feature) beyond three months is to occur no sooner than 61 days and no later than 90 days after initiating therapy. Failure of the beneficiary to consistently use the respiratory equipment for an average of 4 hours per 24-hour period after this time represents non-compliant utilization of the device and a rationale for Medicare to deny its continued coverage (LCD-33800).

Though we appreciate the historical nature of these policy requirements, we must recognize that they do not take into account the characteristics of high intensity NIV. As we have noted above, high intensity ventilation signals the use of high inspiratory pressures with a high backup rate targeted at producing significant reductions in PaCO2. From the evidence presented, it does appear that there is a reasonable likelihood of increased survival or avoidance of rehospitalization when the parameters of this technique are fulfilled regularly by the patient.

High intensity ventilation is characterized by IPAP values typically above 20 cm H2O with backup respiratory rates typically 14-18 breaths per minute with the objective of reducing PaCO2 (Kaminska et al., 2021). We believe that to obtain the required parameters of high intensity NIV, a longer period of time than three months may be needed to determine if continued coverage is warranted for this therapeutic process. It has already been noted that excessive pressures and high backup rates may affect tolerability of NIV (Kaminska et al., 2021). For example, we have mentioned the possibility of adverse cardiac effects of this technique. Though this does not appear to cause a blanket reason to withhold high intensity from appropriate patients with COPD, it does inform treating practitioners regarding potential adverse effects of the use of this therapy in patients with co-morbid heart conditions and the need to follow the heart function of these patients carefully (Duiverman et al., 2017), perhaps utilizing a slower ramp up period

than would be used if prescribing a RAD without the capacity to deliver high intensity NIV.

Moreover, authors have studied the home initiation of high intensity NIV in stable hypercapnic COPD patients targeted at a goal of significant reduction of arterial carbon dioxide (Duiverman, Vonk, Bladder, van Melle, Nieuwenhuis et al., 2020). Besides concluding that the process, with the use of telemedicine, is non-inferior to in-hospital initiation, it was also demonstrated that as home IPAP parameters were increased gradually over a period of six months lower PaCO2 values could be achieved. Based on this finding, we believe that in some individuals, the need to continue the use of a RAD with a backup rate feature for the purpose of delivering high intensity NIV may require a longer period of time than three months to demonstrate that continued coverage is warranted.

Therefore, as we are proposing that a RAD with a backup rate be used to deliver high intensity NIV in the home, we believe that it is prudent to allow a period of up to six months to determine if the patient can tolerate the high pressures and the respiratory rates defining the technique. Furthermore, we propose that in order to ensure the success of continued usage as best as is possible, the beneficiary must demonstrate the ability to utilize the device targeted at CO2 reduction, meaning the device is used at an IPAP > 20 cm H2O and backup respiratory rate of at least 14 breaths per minute, consistently for at least five hours per day. Therefore, while the individual may require an earlier evaluation(s), Medicare will make its decision to continue coverage of the RAD beyond 180-days on an assessment occurring no later than 180-days after RAD therapy is initiated based on the attainment of these parameters and improvement of symptoms and/or PaCO2. Medicare will not continue coverage into the seventh and succeeding months of therapy unless the re-evaluation is performed.

Once successful high intensity ventilation is reached, it must be consistently maintained for an average of at least five hours every 24-hour period at the IPAP and backup rate noted above. Furthermore, the resultant reduction of PaCO2 from baseline and/or reduction of symptoms (headache, fatigue, shortness of breath, confusion) along with the duration and parameters of equipment use must be available in the patient's record on each follow up face to face or virtual visit or at a minimum, every six months.

We are also aware that patients' needs and/or conditions may change as the course of their disease continues. For example, it may be that a patient with chronic stable COPD who qualifies for a RAD with a backup rate feature, may decline the therapy or s/he may attempt to use the therapy for a period of time, perceive it to be unhelpful and reject its further use. Then, after another period of time, or perhaps after an exacerbation with/without hospitalization, the patient may be ready to opt for a new trial of the therapy. The previous refusal to either initiate or continue the NIPPV earlier, would not preclude its use during another trial period; instead, coverage would be at the discretion of the DME MACs.

Moreover, even though it has been demonstrated that adherence to bi-level NIV is better with high pressures than it is with low pressures (Kaminska, Adam & Orr, 2024), we are aware that there will be some individuals who may not desire to use, or be able to tolerate, the parameters of high intensity noninvasive ventilation with a RAD as described above, yet whose PCO2 level and/or symptoms may respond, at least in part, to ventilatory therapy with a RAD at lower intensities. In this case, a backup rate feature would not be necessary. In such circumstances, we believe that the coverage qualifications for the use of a RAD without backup rate feature should be no more restrictive than current coverage and in addition, be as comparable as possible to that proposed for a device with backup rate feature. Therefore, we will allow initial coverage for these devices as long as the patient (1) exhibits persistent hypercapnia as demonstrated by PaCO2 ≥ 52 by arterial blood gas during awake hours while breathing his/her prescribed FiO2; (2) exhibits the physical and cognitive ability to support long term home ventilation (or has a caregiver to assist in this endeavor) and (3) sleep apnea is not the predominant cause of the hypercapnia. Similar to the requirements for a RAD with a backup rate feature, we also propose that while the individual may require an earlier evaluation(s), Medicare will base its decision to continue coverage of the RAD beyond 180-days based on an assessment occurring no later than 180-days after RAD therapy is initiated. Medicare will not continue coverage into the seventh and succeeding months of therapy until the re-evaluation is performed. The device must be utilized for

an average of at least five hours per 24 hour period. Further requirements for continuation of coverage are proposed to mimic those required for use of a RAD with backup feature.

Summary

CMS believes that RADs with a backup rate feature can improve the health outcomes of certain individuals with chronic respiratory failure consequent to COPD when used to deliver high intensity noninvasive ventilation. Therefore, we are proposing to expand coverage of nocturnal bi-level RADs for the treatment of hypercapnia in chronic severe COPD, to allow initiation of RAD therapy with backup rate capability. We are also proposing that individuals with COPD provided a RAD with a backup rate feature used to deliver high intensity NIV, be allowed a period of up to six months to determine if the high pressures and the respiratory rates defining the technique can be tolerated so as to provide signs and symptoms of disease improvement.

For those individuals unable to tolerate high intensity noninvasive ventilation using a RAD with backup feature, criteria for the use and continued coverage of a RAD without backup rate feature are also proposed. These criteria are similar to those for the coverage of a RAD with backup feature.

CMS is also proposing the clinical criteria that describe the need of a home mechanical ventilator, rather than a RAD, for those individuals with severe COPD and hypercapnia.

X. Conclusion

A. General

Respiratory assist devices (RADs) with bi-level capability, with or without a backup rate feature, are devices that use a non-invasive interface (mask) to deliver a higher level of airway pressure when the patient inhales than when the patient exhales. A backup rate feature enables the device to provide a prespecified respiratory rate if the patient's spontaneous respiratory rate decreases below a set number.

Compared with RADs, home mechanical ventilators typically have additional ventilatory modes, monitoring, ventilator control, and safety, alarm, and backup power features (batteries).

B. Proposed Nationally Covered Indications

I. Respiratory Assist Devices (RADs)

(a) Initial Coverage Criteria

(i) RAD with Backup Rate Feature

The Centers for Medicare & Medicaid Services (CMS) proposes to cover a RAD with backup rate feature in the home to deliver high intensity noninvasive ventilation (NIV) as treatment for an individual with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD). A RAD with backup rate feature must be utilized in the high intensity mode (IPAP > 20 cm H2O and backup respiratory rate of at least 14 breaths per minute). A RAD with backup rate feature is covered in the home for an initial 180-day period for individuals with COPD when all the following criteria are met:

- The individual exhibits persistent hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO2;
- Sleep apnea is not the predominant cause of the hypercapnia;
- The individual exhibits the physical and cognitive ability to support home ventilation or has a caregiver who can assist, and
- The individual demonstrates one of the following characteristics:
    - Stable COPD, defined as no increase in or new onset of more than one respiratory symptom (cough, sputum production, sputum purulence, wheezing, or dyspnea) lasting 2 or more days and no change of pharmacological treatment during the 4-week period before initiation of NIV, or
    - Persistent hypercapnia for at least 2 weeks post hospitalization after resolution of an exacerbation of COPD requiring acute NIV.

(ii) RAD without Backup Rate Feature

CMS proposes to cover a RAD without backup rate feature for an individual with CRF consequent to COPD who cannot tolerate high intensity NIV or for whom the backup rate feature is otherwise medically inappropriate. A RAD without backup rate feature is covered in the home for an initial 180-day period for individuals with COPD when all of the following criteria are met:

- The individual exhibits persistent hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO2;
- Sleep apnea is not the predominant cause of the hypercapnia; and
- The individual exhibits the physical and cognitive ability to support home ventilation or has a caregiver who can assist.

(iii) RAD Upon Hospital Discharge

CMS proposes to cover a RAD with or without backup rate feature in the home immediately upon hospital discharge for an initial 180-day period for individuals with acute on CRF due to COPD, if the individual required a RAD within the 24-hour period prior to hospital discharge to avoid rapid symptom exacerbation or rise in PaCO2. The type of RAD covered (with or without backup rate feature) must be the same as that used during the last 24 hours of the inpatient admission.

(b) Continuing Usage Criteria for a RAD

CMS proposes that individuals receiving initial coverage for a RAD as described in (i), (ii) or (iii) above must be re-evaluated by day 180 after receiving a RAD, and at least every 6 months thereafter, to establish that continued coverage by Medicare beyond the first 180-days is medically necessary. Medicare will not continue coverage into the 7th and succeeding months of therapy until the required re-evaluation is performed and establishes that continued coverage is medically necessary.

During a re-evaluation to establish that continued coverage is medically necessary, the practitioner must evaluate and verify that all the following usage requirements are achieved by the beneficiary in order to continue coverage of the device:

- Consistent use of the device for an average of at least 5 hours per 24-hour period, and
- One or more of the following clinical outcomes has been achieved:
    - a normalization of PaCO2, or

- a 20% reduction in PaCO2 from baseline value, or
- a reduction in COPD exacerbations requiring hospitalization due, at least in part, to device usage, or
- an improvement of at least one of the following patient symptoms associated with chronic hypercapnia:
    - Øheadache
    - Øfatigue
    - Øshortness of breath
    - Øconfusion

Note, as described in (i) above, a RAD with backup rate feature must be utilized in the high intensity mode (IPAP > 20 cm H2O and backup respiratory rate of at least 14 breaths per minute).

II. Home Mechanical Ventilators

(a) Initial Coverage Criteria

CMS proposes to cover a home mechanical ventilator (HMV) used in a volume targeted mode as treatment for an individual with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD) who exhibits certain clinical characteristics.

(i) An HMV is covered for an initial 180-day period for individuals with COPD when all of the following criteria are met:

- The individual exhibits persistent hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO2;
- Sleep apnea is not the predominant cause of the hypercapnia;
- The individual exhibits the physical and cognitive ability to support home ventilation or has a caregiver who can assist; and
- The individual demonstrates at least one of the following characteristics:
    - Requires oxygen therapy at an FiO2 ≥36% or ≥ 4L nasally, or
    - Requires ventilatory support for more than 8 hours per 24-hour period, or
    - Requires the alarms and internal battery of a HMV, because the patient is unable to effectively breathe on their own for more than a few hours and the unrecognized interruption of ventilatory support is likely to cause a life-threatening condition if the patient or caregiver cannot be otherwise alerted, or
    - None of the below are likely to be achieved with consistent use of a RAD with backup rate feature for 5 hours per 24-hour period during an adequate trial period because the patient's inspiratory pressure needs exceed the capabilities of a RAD as justified by the patient's medical condition:
        - normalization of PaCO2, or
        - a 20% reduction in PaCO2 from baseline value, or
        - a reduction in COPD exacerbations requiring hospitalization due, at least in part, to device usage has occurred, or
        - an improvement of at least one of the following patient symptoms associated with chronic hypercapnia:
            - Øheadache
            - Øfatigue
            - Øshortness of breath
            - Øconfusion

(ii) Home Mechanical Ventilator Use Upon Hospital Discharge

CMS proposes to cover an HMV used in a volume targeted mode immediately upon hospital discharge for an initial 180-day period for individuals with acute on chronic respiratory failure due to COPD if the beneficiary's needs exceeded the capabilities of a RAD (with or without backup rate feature) and required usage of a ventilator within the 24-hour period prior to hospital discharge to avoid rapid symptom exacerbation or rise in PaCO2.

b) Continuing Usage Criteria for an HMV

CMS proposes that individuals receiving coverage for an HMV as described in (i) and (ii) above must be re-evaluated by day 180 after receiving an HMV, and at least every 6 months thereafter, to establish that continued coverage by Medicare beyond the first 180-days is medical necessity. Medicare will not continue coverage into the 7th and succeeding months of therapy until the required re-evaluation is performed and establishes that continued coverage is medically necessary.

During a re-evaluation to establish that continued coverage is medically necessary, the practitioner must evaluate and verify that the HMV has been used for an average of at least 5 hours per 24-hour period in order to continue coverage of the device.

(c) Masks for HMVs

For those individuals who require the daily use of home mechanical ventilation used in a volume targeted mode for greater than 8 hours per 24-hour period and use an oronasal mask at night, we are proposing to cover, in addition, either mouthpiece ventilation or nasal mask for use during day hours. Note, coverage of such supplies does not exclude coverage of additional supplies used for HMV necessary for the effective use of the HMV.

C. Nationally Non-Covered Indications

N/A

D. Other

Coverage of all other indications for RADs and HMVs used in the treatment of COPD, including subsequent attempts at their usage, not otherwise specified above as covered or non-covered, will be made by local Medicare Administrative Contractors under section 1862(a)(1)(A) of the Act.

See Appendix A for the proposed manual language.

Additionally, we propose to make conforming changes in Section 280.1 (Durable Medical Equipment List) of the National Coverage Determinations (NCD) Manual to add a cross reference to new NCD Section 240.9 (NIPPV in the Home for the Treatment of CRF Consequent to COPD).

CMS is seeking comments on our proposed decision pursuant to §1862(l)(3)(B) of the Act.

APPENDIX A

Medicare National Coverage Determinations Manual

Draft

We are seeking public comments on the proposed language that we would include in the Medicare National Coverage Determinations Manual. This proposed language does not reflect public comments that will be received on the proposed decision memorandum, and which may be revised in response to those comments.

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(Rev.)

A. General

Respiratory assist devices (RADs) with bi-level capability, with or without a backup rate feature, are devices that use a non-invasive interface (mask) to deliver a higher level of airway pressure when the patient inhales than when the patient exhales. A backup rate feature enables the device to provide a prespecified respiratory rate if the patient's spontaneous respiratory rate decreases below a set number.

Compared with RADs, home mechanical ventilators typically have additional ventilatory modes, monitoring, ventilator control, and safety, alarm, and backup power features (batteries).

B. Proposed Nationally Covered Indications

I. Respiratory Assist Devices (RADs)

(a) Initial Coverage Criteria

(i) RAD with Backup Rate Feature

The Centers for Medicare & Medicaid Services (CMS) proposes to cover a RAD with backup rate feature in the home to deliver high intensity noninvasive ventilation (NIV) as treatment for an individual with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD). A RAD with backup rate feature must be utilized in the high intensity mode (IPAP > 20 cm H2O and backup respiratory rate of at least 14 breaths per minute). A RAD with backup rate feature is covered in the home for an initial 180-day period for individuals with COPD when all the following criteria are met:

- The individual exhibits persistent hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO2;
- Sleep apnea is not the predominant cause of the hypercapnia;
- The individual exhibits the physical and cognitive ability to support home ventilation or has a caregiver who can assist, and
- The individual demonstrates one of the following characteristics:
    - Stable COPD, defined as no increase in or new onset of more than one respiratory symptom

(cough, sputum production, sputum purulence, wheezing, or dyspnea) lasting 2 or more days and no change of pharmacological treatment during the 4-week period before initiation of NIV, or
- Persistent hypercapnia for at least 2 weeks post hospitalization after resolution of an exacerbation of COPD requiring acute NIV.

(ii) RAD without Backup Rate Feature

CMS proposes to cover a RAD without backup rate feature for an individual with CRF consequent to COPD who cannot tolerate high intensity NIV or for whom the backup rate feature is otherwise medically inappropriate. A RAD without backup rate feature is covered in the home for an initial 180-day period for individuals with COPD when all of the following criteria are met:

- The individual exhibits persistent hypercapnia as demonstrated by $PaCO_2 \geq 52$ mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO_2;
- Sleep apnea is not the predominant cause of the hypercapnia; and
- The individual exhibits the physical and cognitive ability to support home ventilation or has a caregiver who can assist.

(iii) RAD Upon Hospital Discharge

CMS proposes to cover a RAD with or without backup rate feature in the home immediately upon hospital discharge for an initial 180-day period for individuals with acute on CRF due to COPD, if the individual required a RAD within the 24-hour period prior to hospital discharge to avoid rapid symptom exacerbation or rise in $PaCO_2$. The type of RAD covered (with or without backup rate feature) must be the same as that used during the last 24 hours of the inpatient admission.

(b) Continuing Usage Criteria for a RAD

CMS proposes that individuals receiving initial coverage for a RAD as described in (i), (ii) or (iii) above must be re-evaluated by day 180 after receiving a RAD, and at least every 6 months thereafter, to establish that continued coverage by Medicare beyond the first 180-days is medically necessary. Medicare will not continue coverage into the 7th and succeeding months of therapy until the required re-evaluation is performed and establishes that continued coverage is medically necessary.

During a re-evaluation to establish that continued coverage is medically necessary, the practitioner must evaluate and verify that all the following usage requirements are achieved by the beneficiary in order to continue coverage of the device:

- Consistent use of the device for an average of at least 5 hours per 24-hour period, and
- One or more of the following clinical outcomes has been achieved:
  - a normalization of $PaCO_2$, or
  - a 20% reduction in $PaCO_2$ from baseline value, or
  - a reduction in COPD exacerbations requiring hospitalization due, at least in part, to device usage, or
  - an improvement of at least one of the following patient symptoms associated with chronic hypercapnia:

Øheadache

Øfatigue
Øshortness of breath
Øconfusion

Note, as described in (i) above, a RAD with backup rate feature must be utilized in the high intensity mode (IPAP > 20 cm H2O and backup respiratory rate of at least 14 breaths per minute).

II. Home Mechanical Ventilators

(a) Initial Coverage Criteria

CMS proposes to cover a home mechanical ventilator (HMV) used in a volume targeted mode as treatment for an individual with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD) who exhibits certain clinical characteristics.

(i) An HMV is covered for an initial 180-day period for individuals with COPD when all of the following criteria are met:

- The individual exhibits persistent hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO2;
- Sleep apnea is not the predominant cause of the hypercapnia;
- The individual exhibits the physical and cognitive ability to support home ventilation or has a caregiver who can assist; and
- The individual demonstrates at least one of the following characteristics:
    - Requires oxygen therapy at an FiO2 ≥36% or ≥ 4L nasally, or
    - Requires ventilatory support for more than 8 hours per 24-hour period, or
    - Requires the alarms and internal battery of a HMV, because the patient is unable to effectively breathe on their own for more than a few hours and the unrecognized interruption of ventilatory support is likely to cause a life-threatening condition if the patient or caregiver cannot be otherwise alerted, or
    - None of the below are likely to be achieved with consistent use of a RAD with backup rate feature for 5 hours per 24-hour period during an adequate trial period because the patient's inspiratory pressure needs exceed the capabilities of a RAD as justified by the patient's medical condition:
        - normalization of PaCO2, or
        - a 20% reduction in PaCO2 from baseline value, or
        - a reduction in COPD exacerbations requiring hospitalization due, at least in part, to device usage has occurred, or
        - an improvement of at least one of the following patient symptoms associated with chronic hypercapnia:
            Øheadache
            Øfatigue
            Øshortness of breath
            Øconfusion

(ii) Home Mechanical Ventilator Use Upon Hospital Discharge

CMS proposes to cover an HMV used in a volume targeted mode immediately upon hospital discharge for an initial 180-day period for individuals with acute on chronic respiratory failure due to COPD if the beneficiary's needs exceeded the capabilities of a RAD (with or without backup rate feature) and required

usage of a ventilator within the 24-hour period prior to hospital discharge to avoid rapid symptom exacerbation or rise in PaCO2.

b) Continuing Usage Criteria for an HMV

CMS proposes that individuals receiving coverage for an HMV as described in (i) and (ii) above must be re-evaluated by day 180 after receiving an HMV, and at least every 6 months thereafter, to establish that continued coverage by Medicare beyond the first 180-days is medical necessity. Medicare will not continue coverage into the 7th and succeeding months of therapy until the required re-evaluation is performed and establishes that continued coverage is medically necessary.

During a re-evaluation to establish that continued coverage is medically necessary, the practitioner must evaluate and verify that the HMV has been used for an average of at least 5 hours per 24-hour period in order to continue coverage of the device.

(c) Masks for HMVs

For those individuals who require the daily use of home mechanical ventilation used in a volume targeted mode for greater than 8 hours per 24-hour period and use an oronasal mask at night, we are proposing to cover, in addition, either mouthpiece ventilation or nasal mask for use during day hours. Note, coverage of such supplies does not exclude coverage of additional supplies used for HMV necessary for the effective use of the HMV.

C. Nationally Non-Covered Indications

N/A

D. Other

Coverage of all other indications for RADs and HMVs used in the treatment of COPD, including subsequent attempts at their usage, not otherwise specified above as covered or non-covered, will be made by local Medicare Administrative Contractors under section 1862(a)(1)(A) of the Act.

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[1] The overall average score reflects the votes of all persons who sit on the MEDCAC Panel, including guest panelists with topic expertise.

[2] The current Medicare coverage requirements for RADs (with or without a backup feature) state that beneficiaries must be re-evaluated to establish the medical necessity of continued coverage of the device beyond the first three months. While the beneficiary may need to be evaluated at earlier intervals after RAD therapy is initiated, the re-evaluation upon which Medicare will base a decision to continue coverage beyond this time must occur no sooner than 61 days after initiating therapy by the treating practitioner. Medicare will not continue coverage for the fourth and succeeding months of therapy until this re-evaluation has been completed.

There must be documentation in the beneficiary's medical record about the progress of relevant symptoms and beneficiary usage of the device up to that time. Failure of the beneficiary to be consistently using the RAD device for an average of 4 hours per 24 hour period by the time of the re-evaluation (on or after 61 days after initiation of therapy) would represent non-compliant utilization for the intended purposes and expectations of benefit of this

therapy. This would constitute reason for Medicare to deny continued coverage as not reasonable and necessary (LCD-33800 Respiratory Assist Devices)

[3] The assist/control mode allows for a patient to trigger a ventilator, but also allows for a backup respiratory rate to be set. If the patient's spontaneous frequency of breathing is lower than the pre-set backup rate, the patient will follow the settings of the ventilator (Rabec et al., 2011).

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