CHEST

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

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This document summarizes the work of the COPD Technical Expert Panel working group. For patients with COPD, the most pressing current coverage barriers identified were onerous diagnostic requirements focused on oxygenation (rather than ventilation) and difficulty obtaining bilevel devices with backup rate capabilities. Because of these difficulties, many patients with COPD were instead sometimes prescribed home mechanical ventilators. Critical evidence supports changes to current policies, including randomized controlled trial evidence suggesting a mortality benefit from bilevel positive airway pressure with backup rate and updated clinical practice guidelines from the American Thoracic Society as well as the European Respiratory Society. To achieve optimal access to noninvasive ventilation for patients with COPD, we make the following key recommendations: (1) removal of the need for overnight oximetry testing; (2) the ability to initiate therapy using bilevel devices with backup rate capability; and (3) increased duration of time to meet adherence criteria (ie, a second 90-day trial period) in those patients actively engaged in their care. Clear guidelines based on medical necessity are also included for patients who require initiation of or switch to a home mechanical ventilator. Adoption of these proposed recommendations would result in the right device, for the right type of patient with COPD, at the right time. Finally, we emphasize the need for adequate clinical support during initiation and maintenance of home noninvasive ventilation in such patients.

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KEY WORDS: COPD; hypercapnic respiratory failure; mechanical ventilation; noninvasive ventilation

ABBREVIATIONS: ABG = arterial blood gas; BPAP = bilevel positive airway pressure device; CMS = Centers for Medicare & Medicaid Services; HMV = home mechanical ventilator; NIV = noninvasive ventilation; ONMAP = Optimal NIV Medicare Access Promotion; TEP = Technical Expert Panel

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Note to the Reader: The current document is one of a series produced by a Technical Expert Panel (TEP), whose purpose was to propose changes to Centers for Medicare & Medicaid Services national coverage determinations for the use of noninvasive ventilation and home mechanical ventilation, which were formulated in 1998. Specifically, the TEP proposed changes to national coverage determinations for thoracic restrictive disorders (neuromuscular disease), COPD, hypoventilation syndromes, central sleep apnea, and OSA. The background, makeup of the TEP, and key recommendations are highlighted in an Executive Summary. CHEST, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society formed the "Optimal NIV Medicare Access Promotion (ONMAP)" to provide processes to obtain the "right device for the right patient at the right time." More details and rationale for the proposed changes are available in the companion documents.

There are an estimated 24 million people with COPD in the United Sates. COPD is the third or fourth leading cause of death,[1,2] and the cost of caring for patients with COPD in the United States was calculated at $49 billion dollars in 2020 (https://www.cdc.gov/copd/infographics/copd-costs.html). COPD leads to deterioration of lung function over decades, and when obstruction becomes severe ($FEV_1 < 50\%$), it is often accompanied by gas exchange abnormalities, including $\dot{V}/\dot{Q}$ mismatch and increased dead space, which impair the ability to maintain normal oxygenation and alveolar ventilation.[3] Once hypoxemia during wakefulness reaches critical levels ($Pao_2 < 55$ mm Hg), supplemental oxygen improves survival.[4] Impairment of alveolar ventilation predisposes to progressive hypercapnia as compensatory mechanisms fail, initially during sleep but eventually becoming diurnal.[5] In these cases, a rise in $Paco_2$ above the normal threshold of 45 mm Hg is independently associated with increased mortality.[6] Studies have shown that use of noninvasive positive pressure ventilatory support via a mask to lower $Paco_2$ in these patients lowers mortality and reduces hospitalizations.[7,8]

This review summarizes the status of Centers for Medicare & Medicaid Services (CMS) coverage policies for use of noninvasive ventilation (NIV) for COPD, highlighting the problems with the policies that create barriers to NIV use and that encourage its inappropriate applications. We provide recommendations for solutions to these problems.

Background

Current Coverage Guidelines

For patients with severe COPD, current coverage criteria need to be satisfied (Local Coverage Determination: Respiratory Assist Devices [L33800; https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33800]). These criteria qualify a patient for a respiratory assist device, or "RAD," without a backup rate (ie, a bilevel positive airway pressure device [BPAP] in the spontaneous mode that requires the patient to initiate all breaths spontaneously). The RAD terminology was a creation of CMS and exists nowhere else in the clinical literature, and it needs to be eliminated in the future. A BPAP with a backup rate (spontaneous/timed mode) would be covered if, after 2 months, the patient was using the device for > 4 h of 24 h, symptoms persisted, $Paco_2$ remained 52 mm Hg or above, AND overnight oxygen saturation was $\leq 88\%$ for > 5 min on the usual Fio_2.

The Problem: Patients Not Receiving Appropriate Devices: In August 2003, the reimbursement ruling was changed to ensure that all BPAPs, even when used as a ventilator with a backup rate, were nevertheless paid as a capped rental item; that is, payments stop after 13 months, and the device becomes the property of the patient. This ruling clarified the reimbursement policy for BPAPs vs home mechanical ventilators (HMVs), which are defined as devices that need frequent and substantial servicing, and discontinuation would lead to imminent death of the patient.

Some 17 years later, technological advances have led to overlap of the two categories of devices (BPAPs and HMVs) used to treat patients with chronic hypercapnic respiratory failure. HMVs have internal batteries, more sophisticated monitoring and alarms, and greater pressure-generating capabilities than BPAPs, but both devices can provide BPAP settings as well as volume-targeted modes. In the past, the ability to provide volume-targeted modes distinguished ventilators from BPAPs, but with the advent of modes such as volume-assured pressure support, this distinction is now blurred. It is now more difficult to tie device reimbursement to medically necessary treatment plans chosen for one patient or another when BPAP settings are deliverable with either a BPAP or an HMV. Moreover, the current qualification criteria for using a BPAP device may create greater barriers to approval than with an HMV (see below). This factor, in combination with the fact that HMVs are reimbursed by CMS at higher rates than

BPAPs and without a cap, has led to a large increase in the utilization of HMVs and a huge rise in expenditures in the COPD population over the past 5 years, as discussed in the Executive Summary.

As outlined here, the problems with the current national coverage determination for NIV in COPD can best be described by using case vignettes illustrating the barriers the current criteria can pose as clinicians struggle to provide the appropriate device.

1. Overnight oxygen saturation $\leq$ 88% for $>$ 5 min, with a minimum of 2 h of nocturnal recording on 2 L/min of supplemental oxygen or the patient's prescribed level, whichever is higher.

Vignette: J. M. is a 64-year-old woman who has severe COPD and chronic hypercapnic respiratory failure requiring 2 L/min continuous oxygen therapy. During her usual chronic stable state, arterial blood gas (ABG) is checked, and the $Paco_2$ is 52 mm Hg. A nocturnal oxygen assessment is ordered while she uses her usual 2 L/min of oxygen via nasal prongs and shows no oxygen saturations $\leq$ 88% for 5 min. She is told she does not qualify for NIV and wonders if there are any other therapies for her that could improve her quality and length of life.

This criterion is not physiologically sound. Use of oxygen supplementation during sleep is likely to mask CO_2 elevations, leading to nocturnal normoxia despite moderate or even severe nocturnal hypercapnia. One study of patients with COPD and a resting $Paco_2$ $>$ 52 mm Hg (mean $Paco_2$ of 61.5 mm Hg) had persistent hypercapnia with a median partial pressure of CO_2 in venous blood of 69.5 mm Hg and end-tidal CO_2 of 41.5 mm Hg despite normal blood oxygen saturation (Fig 1).[9] None of the patients had desaturations $<$ 90% despite their persistent hypercapnia. Furthermore, no studies on use of NIV for severe stable COPD or following a severe exacerbation have used this criterion for inclusion, and there is a complete lack of evidence to support it. To deny NIV, which could provide the benefits the patient is seeking, based on a lack of nocturnal oxygen desaturations while on supplemental oxygen is problematic and without any scientific justification. This either prevents patients from receiving potentially beneficial therapy or forces prescribers to ask for ventilators that offer more technology and are more costly. The nocturnal oximetry requirement must be removed.

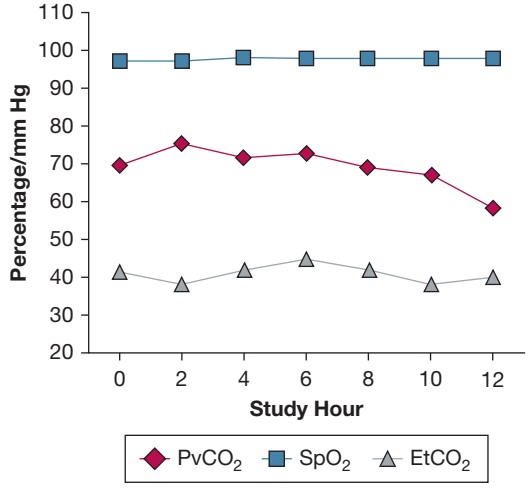

Figure 1 – *Severe nocturnal hypercapnia despite normoxia in hospitalized patients with COPD receiving supplemental nasal oxygen at 2 L/min. $EtCO_2$ = end-tidal CO_2; Spo_2 = oxygen saturation by pulse oximetry; $Pvco_2$ = venous Pco_2.*

2. When should an HMV be considered instead of BPAP therapy?

Vignette: A 65-year-old woman presents with increased fatigue, shortness of breath, and lower extremity edema. She has had no increased cough or phlegm recently, and no recent hospitalizations. The FEV_1 is 24% of predicted, and she is on 4 L/min of oxygen via nasal prongs at rest. ABG shows a $Paco_2$ of 64 mm Hg and serum bicarbonate of 38 mEq/L. The patient is started on BPAP NIV with inspiratory pressure of 18 cm H_20. She reports inspiratory discomfort and air leakage, and averages 4.5 h of use nightly; the device has no capability to better optimize the flow delivery. One month later, the patient is feeling no better and is very fatigued in the morning. Repeat ABG shows a $Paco_2$ of 62 mm Hg and serum bicarbonate of 37 mEq/L. She is switched to an HMV in volume-assured pressure support mode targeting a tidal volume of 8 mL/kg, inspiratory pressure range of 28 cm H_2O maximum and 12 cm H_2O minimum, and a backup rate of 15 breaths/min. On these settings, she sleeps better at night and has more energy during the day. An ABG reveals $Paco_2$ of 50 cm H_2O with bicarbonate of 32 mEq/L.

HMVs should be considered in patients with persistent hypercapnia above the targeted goals for ventilation despite BPAP support at therapeutic levels and in those patients with significant dyssynchrony with BPAP support and those with oxygenation requirements that cannot be met by BPAP devices. They should also be considered in those who require inspiratory positive airway pressure levels $>$ 25 cm H_2O (ie, greater than what can be delivered by most E0471 devices) or can

also be considered in patients who have an unreliable power source and would benefit from the backup batteries. Other patients likely to benefit include those with severe hypoxemia requiring F_{IO_2} > 40% or > 5 L/min, those requiring daytime ventilator support (ie, > 10 h per day or mouthpiece ventilation), and those who need more sophisticated alarms. As with patients with thoracic restrictive disorders, these patients can be most easily identified by their high ventilatory needs requiring extended ventilation times into the *daytime hours*. Moreover, the patient with COPD struggles even more from severe gas exchange abnormalities with hypoxemia. Their required therapy is not successfully satisfied with current BPAP equipment.

A separate clinical issue, not addressed under current policy, is the lack of provision to ensure expert clinical support of a respiratory therapist in the home. This may lead to failure of home ventilatory support and the transfer of some patients with more complex chronic respiratory failure to a chronic care facility. This action detracts from the patient's well-being and increases costs to the health care system. The core of the problem is that the current reimbursement policy forces a disconnect between the patient's clinical status/needs and reimbursement because payment policies are locked into devices rather than the clinical situation.[10] This is more fully addressed in a commentary below.

Current Evidence/Guidelines

Since the current coverage criteria were enacted, new crucial evidence has accrued, and technology has evolved. It is time to critically re-examine the guidelines and suggest alterations that will facilitate the delivery of the right device to the right patient at the right time.

Past studies on the nocturnal home use of BPAP ventilation to treat chronic respiratory failure in COPD provided variable and often conflicting results.[11] In 2014, Kohnlein et al[7] published a landmark prospective, multicenter, randomized controlled trial of BPAP ventilation compared with optimized standard therapy in patients with chronic stable hypercapnic COPD. Patients had stage IV COPD and a mean age of 64.4 years, with resting $P_{aCO_2} \geq$ 51.9 mm Hg and pH > 7.35. BPAP ventilation was targeted to reduce baseline P_{aCO_2} by at least ≥ 20%, or to achieve values < 48 mm Hg, using high inspiratory pressures and a backup rate. The difference in 1-year all-cause mortality was profound, with 12% in the BPAP group and 33% in the control group (Fig 2).

Secondary improvements were also seen in FEV_1, P_{aCO_2}, and pH in the BPAP group compared with the control

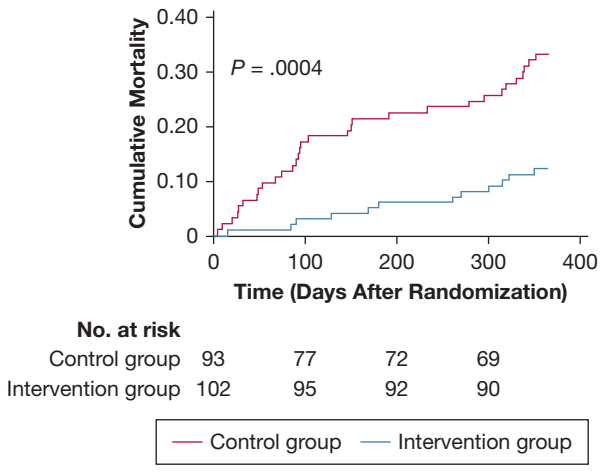

Figure 2 – *Effect of noninvasive ventilation with backup rate vs oxygen therapy alone on survival in stable severe hypercapnic COPD. (From Kohnlein et al.[7]).*

group.[7] No intervention-related complications were reported except for facial skin rash in 14% of patients. Quality of life also improved. The effect of BPAP on overall survival in patients with chronic hypercapnic COPD was believed to be related to the use of a high inspiratory pressure and backup rate (termed high-intensity ventilation). The rationale for the backup rate is that it helps to sustain nocturnal ventilation in the face of physiological suppression of respiratory drive during sleep, which, combined with diaphragm dysfunction related to hyperinflation, can lead to hypoventilation and failure to trigger, especially during rapid eye movement sleep.

Another approach to initiating BPAP in patients with severe COPD is to intervene following an admission for acute respiratory failure. This has garnered additional interest because of concerns regarding hospital readmission rates in patients with COPD. Murphy et al[8] used this approach, enrolling 116 patients with mean age of 66.7 years and persisting hypercapnia (> 53 mm Hg), at least 2 weeks following resolution of decompensated acidosis and within 4 weeks of attaining clinical stability following a hospitalization that required use of acute NIV. Patients were randomized to receive high-pressure NIV (average inspiratory pressure 24 cm H_2O, expiratory pressure 4 cm H_2O with a backup rate of 14 breaths/min) with home oxygen therapy or home oxygen therapy alone. The primary outcome, hospital admission or death, was again significantly different, with home oxygen therapy patients requiring readmission following a median of 1.4 months' postdischarge compared with 4.3 months for patients using BPAP ventilation. One-year mortality was not

significantly different between the groups, but transcutaneous P_{CO_2} and frequency of exacerbations were reduced and quality of life improved in the BPAP group. Another similarly designed study by Struik et al[12] found no significant differences in readmissions or mortality, although these patients did not manifest persistent hypercapnia.

These data provide important information regarding: (1) the level of resting hypercapnia in patients likely to benefit from home NIV; (2) the lack of need to perform a sleep study or nocturnal oximetry to select patients with COPD and a BMI < 35 kg/m^2 for successful NIV; and (3) the importance of using higher inspiratory pressure settings/pressure support level than older studies and the addition of backup respiratory breaths to achieve a reduction in $Paco_2$. Although surrogate $Paco_2$ measurements such as end-tidal or transcutaneous options may be appropriate for patients with thoracic restrictive disorders or other hypoventilation syndromes, an ABG with a $Paco_2$ is necessary for patients with COPD to identify the hypoventilatory threshold ($Paco_2 \geq 52$ mm Hg) expected to benefit from NIV, based on the aforementioned literature and expert opinion. Whether surrogate measurements of $Paco_2$ can be used for qualifying patients with COPD for home NIV or for monitoring subsequent responses remains to be established.

The findings from the clinical studies described here have been substantiated by Frazier et al[13] using the Medicare Limited Data Set (2012-2018). They compared 517 patients with COPD started on NIV within 2 months of receiving a diagnosis of chronic respiratory failure vs 511 patients with COPD matched for demographic and clinical characteristics but who were not started on NIV. One year following diagnosis, mortality in the NIV group was 28% vs 46% in the control subjects. The relative risk reduction attributable to NIV was 39% for mortality, 17% for hospitalizations, and 22% for ED visits.

In 2019, the Agency for Healthcare Research and Quality contracted for a technology assessment of NIV in the home. Based on a systematic review of the literature, the task force concluded that for COPD, BPAP reduced dyspnea and mortality and increased activities of daily living, whereas both BPAP and HMV reduced hospitalizations.[14]

The European Respiratory Society Task Force in 2019[15] and an American Thoracic Society subcommittee in 2020[16] both suggested using long-term home NIV for stable hypercapnic COPD as well as for patients with COPD following hospitalization for an exacerbation requiring NIV. The American Thoracic Society guideline suggested waiting for at least 2 weeks to assure persistence of hypercapnia (conditional recommendation, very low certainty), whereas the European Respiratory Society suggested that reassessment could be considered but was not necessary and seemed to suggest it should be left up to the discretion of the treating physician. The Technical Expert Panel (TEP) agrees with the European Respiratory Society recommendation that the timing of intervening with NIV following hospitalization should be left to the clinician's discretion. Both guidelines also recommended ventilator settings to reduce $Paco_2$, with the American Thoracic Society guideline suggesting to "target normalization." The European Respiratory Society guideline also suggested "fixed pressure support" as the preferable mode.

Optimal NIV Medicare Access Promotion (ONMAP): New National Coverage Determination for BPAP Devices in COPD

1. Removal of the requirement for a nocturnal oximetry study using either 2 L/min nasal oxygen or the patient's usual Fio_2, whichever is higher.
2. Removal of the requirement that patients start with a BPAP device without a backup rate.

Replace with:

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

1. ABG while awake and receiving supplemental oxygen (if prescribed) displaying a $Paco_2 \geq 52$ mm Hg.
2. OSA and CPAP treatment have been considered and ruled out (formal testing not required; this only requires clinical documentation).
3. Patients with severe hypercapnic COPD should be considered for an HMV under the following circumstances if they need any of the following:
   - Higher inspiratory pressures than those deliverable by E0471
   - Fio_2 higher than 40% or 5 L/min nasally
   - Ventilator support for 10 h per day or greater (ie, daytime use)
   - Both sophisticated alarms and accompanying internal battery (high-dependency patient)

- Mouthpiece ventilation during the day
- Persistence of hypercapnia with $Paco_2$ $\geq$ 52 mm Hg despite adequate adherence to BPAP therapy

Adherence and Monitoring of NIV in COPD

Initiation

Initiation of long-term NIV may occur in the hospital setting, usually following use of NIV acutely for an exacerbation, or at home in a patient with stable chronic hypercapnia. Whether in-hospital initiation of NIV, as is favored in Europe, is preferable to home initiation, as is favored in the United States, has not been firmly established. A randomized controlled trial from The Netherlands showed noninferiority of home initiation compared with in-hospital initiation of NIV for severe stable COPD.[17] Reduction in $Paco_2$ over 6 months, the major outcome variable, was similar in the two groups, overall costs were halved in the home group, and patients preferred initiation in the home. The home group was contacted frequently by trained nurses, and telemedicine was used to monitor patients in the home.

Over the past two decades, the hardware and software of home ventilators have undergone major technical advances. In addition to pressure support and BPAP spontaneous/timed modes, volume-assured pressure support, autotitrating expiratory positive airway pressure, and built-in algorithms profiled for certain pathologies are now standard options on many ventilators. More importantly, built-in software provides important information for monitoring the efficacy of NIV (ie, estimation of leaks, tidal volume, percentage of cycles triggered and cycled by the ventilator, adherence). This allows a better capacity to facilitate, monitor, and assess the benefits of the therapy.[18]

Adherence

Some studies have reported lower adherence to NIV in patients with COPD compared with those with neuromuscular disease[19] and others show similar rates of adherence, with 30% using the device $<$ 4 h per day and 13% abandoning the therapy altogether within 28 months.[20] The importance of adherence is highlighted by a study of 1,746 patients on NIV for hypercapnic respiratory failure followed up over 6 years, of whom 20% had obstructive lung disease. The single most important factor associated with a poor outcome was low adherence (NIV use $<$ 4 h per day).[21] For this reason, we recommend adaptation of adherence criteria as proposed in the other TEP reports, including the second 90-day trial period for those patients not meeting initial adherence criteria for continued coverage who return at least twice to a treating physician and see benefit from continued use. Rehospitalization would constitute criteria for a new HMV initiation trial even in those previously failing to meet adherence criteria.

Monitoring

Overall, the recommendations for follow-up of patients with COPD using NIV in the home include the following elements: (1) clinical assessment by experienced personnel familiar with the consequences of COPD and NIV use; (2) ABG $Paco_2$ for response and aid to ventilator adjustment guidance to meet the evolving needs of the patient; (3) nocturnal pulse oximetry as a dynamic complement (for monitoring only, not initiation) to the ABG; and (4) trend report, including patterns of use, synchrony and triggered breaths, respiratory rate and tidal volume, minute volume, and leaks from ventilator software, which is now available in most modern devices.

Need for Clinical Support of Patients With COPD Using NIV

We fully recognize that the Medicare durable medical equipment benefit does not provide clinical support for NIV equipment in the home as a separately billable service. However, it is clear to the medical community that such services are essential for safe and effective delivery of NIV. Without such support, patients are at high risk for ineffective device performance that will compromise clinical efficacy and ultimately lead to excessive patient morbidity and even mortality. This is especially important given the fact that durable medical equipment quality standards require a respiratory therapist to be available 24/7 with respect to the use of respiratory equipment. Numerous states also require qualified clinicians (eg ,respiratory therpists) to perform clinical assessments in addition to placing any patient on the device when engaged in the initial set-up and education of the patient and/or caregiver regarding the equipment.

As an example, a review of the experience of long-term home NIV in the Lake Geneva area of Switzerland enrolled 479 patients over 15 years and followed up with them for a median of 39 months.[22] COPD constituted the largest individual group (28%); overall, 82% were

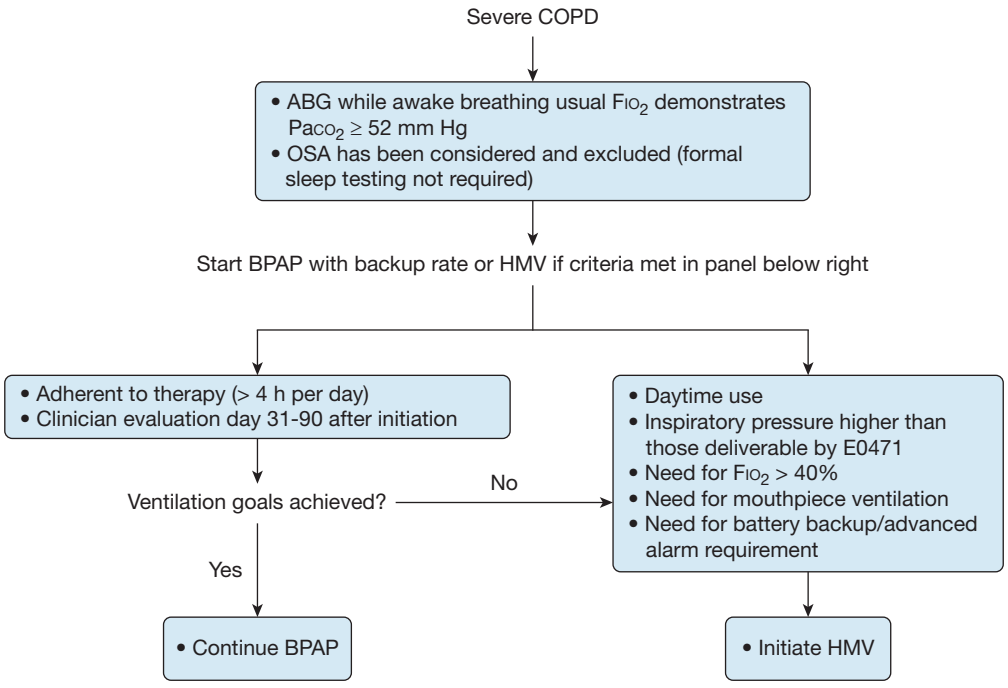

Figure 3 – *Suggested management of patients with COPD who require noninvasive ventilation. ABG = arterial blood gas; BPAP = bilevel positive airway pressure; HMV = home mechanical ventilator.*

initiated on NIV in the hospital and the rest in the outpatient setting. Comorbidities were very common in the patients with COPD; 68% had hypertension, 46% were obese, and 21% had probable pulmonary hypertension. In that cohort, adherence was excellent; only 8% of patients used NIV $<$ 3 h per day, likely because of excellent patient follow-up, either hospital based or by an outpatient pulmonologist. Thus, to achieve optimal adherence, clinical resources will need to be available for these medically complex patients.

Our specific comments are as follows:

1. Initial NIV set-up. To provide effective respiratory support, NIV devices must interact with patient breathing efforts throughout the ventilatory cycle. Specifically, the patient must exert enough effort to initiate a breath and must synchronize with the device to assure adequate pressure and flow delivery throughout the breath. Patients with COPD have severely deranged lung mechanics leading to pronounced dyspnea and anxiety. This can make the NIV set-up process very complex, often requiring multiple adjustments and assessment of responses. Initial NIV set-up in such complex patients cannot be accomplished during short outpatient clinic visits and certainly not by use of prerecorded/printed material alone.[17] We advocate for the provision of frequent visits to the patient's home by skilled qualified clinicians (eg respiratory therpists) who can then make the necessary adjustments to optimize the likelihood of success.
2. Ongoing NIV use. The natural history of COPD is progressive functional deterioration punctuated by exacerbations. This means that NIV support is not static and must be capable of adapting to changing patient conditions and other medical interventions (eg, change in respiratory medications, use of supplemental oxygen). Patients cannot be expected to make these adjustments on their own. Moreover, although physicians (or their assistants) in outpatient settings may occasionally be able to troubleshoot or reset devices via telephone or telemedicine, these tasks are more reliably performed via home face-to-face visits in which both the ventilator and patient can be observed directly. Dedicated qualified clinicians (eg respiratory therapists) who are experts in NIV operations are needed both on 24-h hot lines as well as being readily accessible for in-home visits.
3. A strong evidence base supports the necessity of ongoing clinical/technical support for these patients. The 2020 Agency for Healthcare Research and Quality evidence-based review identified 36 studies

showing benefit of NIV in patients with hypercapnic COPD. These studies extended up to 48 months, and all of them had ongoing clinical/technical support of some form for the duration of the trial.[14] This is also a common clinical practice and the standard of care in most European NIV programs. In the United States, respiratory therapy services in the home are not reimbursed, making it difficult to provide these services, especially for patients on NIV via BPAP.

4. The COPD TEP concluded that the expertise of experienced clinicians (eg, respiratory therapists) to provide the needed support for individuals on home NIV is critical to patient care and avoidance of risk to the patient, whether patients are using BPAP or HMV. We would strongly urge CMS to work with the medical community to find ways to provide this essential element of care for Medicare beneficiaries in the home who are ventilated.

Summary of New Recommendations

The flow diagram presented in Figure 3 summarizes our recommended requirements for coverage of BPAP and HMV in patients with COPD with chronic hypercapnic respiratory failure. We advocate persistent hypercapnia as the main determinant of candidacy without the requirement for nocturnal oximetry and initiation of NIV using a BPAP device with a backup rate. We also provide criteria that would justify initiating NIV with an HMV as outlined in Figure 3.

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References

1. Vogelmeier CF, Criner GJ, Martinez FJ, et al. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Lung Disease 2017 Report. GOLD Executive Summary. *Am J Respir Crit Care Med*. 2017;195(5):557-582.
2. Roth GA, Abate D, Abate HK, et al. Global, regional, and national age-sex-specific mortality for 282 causes of death in 195 countries and territories, 1980-2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet*. 2018;392(10159):736-788.
3. Celli BR, Wedzicha JA. Update on clinical aspects of chronic obstructive pulmonary disease. *N Engl J Med*. 2019;381(13):1257-1266.
4. Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease: a clinical trial. Nocturnal Oxygen Therapy Trial Group. *Ann Intern Med*. 1980;93(3):391-398.
5. Turkington PM, Elliott MW. Rationale for the use of non-invasive ventilation in chronic ventilatory failure. *Thorax*. 2000;55(5):417-423.
6. Ahmadi Z, Bornefalk-Hermansson A, Franklin KA, Midgren B, Ekström MP. Hypo- and hypercapnia predict mortality in oxygen-dependent chronic obstructive pulmonary disease: a population-based prospective study. *Respir Res*. 2014;15(1):30.
7. Kohnlein T, Windisch W, Kohler D, et al. Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomized, controlled clinical trial. *Lancet Respir Med*. 2014;2(9):698-705.
8. Murphy PB, Rehal S, Arbane G, et al. Effect of home noninvasive ventilation with oxygen therapy vs oxygen therapy alone on hospital readmission or death after an acute COPD exacerbation: a randomized clinical trial. *JAMA*. 2017;317(21):2177-2186.
9. Kim C, Marchetti N, Criner GJ. Nocturnal hypercapnia and acidosis despite normoxemia in patients hospitalized for exacerbation of chronic obstructive pulmonary disease. *Am J Respir Crit Care Med*. 2016;193:A5190.
10. King AC. Long-term home mechanical ventilation in the United States. *Respir Care*. 2012;57(6):921-932.
11. Struik FM, Lacasse Y, Goldstein R, Kerstjens HAM, Wijkstra PJ. Nocturnal non-invasive positive pressure ventilation for stable chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. 2013;2013(6):CD002878.
12. Struik FM, Sprooten RT, Kerstjens HA, et al. Nocturnal non-invasive ventilation in COPD patients with prolonged hypercapnia after ventilatory support for acute respiratory failure: a randomised, controlled, parallel-group study. *Thorax*. 2014;69(9):826-834.
13. Frazier WD, Murphy R, van Eijndhoven E. Non-invasive ventilation at home improves survival and decreases healthcare utilization in Medicare beneficiaries with chronic obstructive pulmonary disease with chronic respiratory failure. *Respir Med*. 2021;177:106291.
14. Wilson ME, Dobler CC, Morrow AS, et al. Association of home noninvasive positive pressure ventilation with clinical outcomes in chronic obstructive pulmonary disease: a systematic review and meta-analysis. *JAMA*. 2020;323(5):455-465.
15. Ergan B, Oczkowski S, Rochwerg B, et al. European Respiratory Society guidelines on long-term home non-invasive ventilation for management of COPD. *Eur Respir J*. 2019;54(3):1901003.
16. Macrea M, Oczkowski S, Rochwerg B, et al; on behalf of the American Thoracic Society Assembly on Sleep and Respiratory Neurobiology. Long-term noninvasive ventilation in chronic stable hypercapnic chronic obstructive pulmonary disease. An official American Thoracic Society Clinical Practice Guideline: executive summary. *Am J Respir Crit Care Med*. 2020;202(4):e74-e87.12.
17. Duiverman ML, Vonk JM, Bladder G, et al. Home initiation of chronic noninvasive ventilation in COPD patients with chronic

hypercapnic respiratory failure: a randomised controlled trial. *Thorax*. 2020;75(3):244-252.

18. Janssens JP, Borel JC, Pepin JL; SomnoNIV Group. Nocturnal monitoring of home non-invasive ventilation: the contribution of simple tools such as pulse oximetry, capnography, built-in ventilator software and autonomic markers of sleep fragmentation. *Thorax*. 2011;66(5):438-445.
19. Criner GJ, Brennan K, Travaline JM, Kreimer D. Efficacy and compliance with noninvasive positive pressure ventilation in patients with chronic respiratory failure. *Chest*. 1999;116(3):667-675.
20. Borel JC, Pepin JL, Pison C, et al. Long-term adherence with non-invasive ventilation improves prognosis in obese COPD patients. *Respirology*. 2014;19(6):857-865.
21. Patout M, Lhuillier E, Kaltsakas G, et al. Long-term survival following initiation of home non-invasive ventilation: a European study. *Thorax*. 2020;75(11):965-973.
22. Cantero C, Adler D, Pasquina P, et al. Long-term noninvasive ventilation in the Geneva Lake area: indications, prevalence, and modalities. *Chest*. 2020;158(1):279-291.