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Executive Summary

Optimal NIV Medicare Access Promotion: 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

*Peter C. Gay, MD; Robert L. Owens, MD; on behalf of the ONMAP Technical Expert Panel**

The current national coverage determinations (NCDs) for noninvasive ventilation for patients with thoracic restrictive disorders, COPD, and hypoventilation syndromes were formulated in 1998. New original research, updated formal practice guidelines, and current consensus expert opinion have accrued that are in conflict with the existing NCDs. Some inconsistencies in the NCDs have been noted, and the diagnostic and therapeutic technology has also advanced in the last quarter century. Thus, these and related NCDs relevant to bilevel positive airway pressure for the treatment of OSA and central sleep apnea need to be updated to ensure the optimal health of patients with these disorders. To that end, the American College of Chest Physicians organized a multisociety (American Thoracic Society, American Academy of Sleep Medicine, and American Association for Respiratory Care) effort to engage experts in the field to: (1) identify current barriers to optimal care; (2) highlight compelling scientific evidence that would justify changes from current policies incorporating best evidence and practice; and (3) propose suggestions that would form the basis for a revised NCD in each of these 5 areas (thoracic restrictive disorders, COPD, hypoventilation syndromes, OSA, and central sleep apnea). The expert panel met during a 2-day virtual summit in October 2020 and subsequently crafted written documents designed to achieve provision of "the right device to the right patient at the right time." These documents have been endorsed by the participating societies following peer review and publication in *CHEST* and will be used to inform efforts to revise the current NCDs.

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KEY WORDS: access; Medicare; noninvasive; optimal; ventilation

ABBREVIATIONS: AASM = American Academy of Sleep Medicine; ABG = arterial blood gas; BPAP = bilevel positive airway pressure; CMS = Centers for Medicare & Medicaid Services; CSA = central sleep apnea; DME = durable medical equipment; EPAP = expiratory positive airway pressure; Et_{CO_2} = end-tidal measurement of PCO_2; HMV = home mechanical ventilator; MAC = medical administrative carrier; NCD = national coverage determination; NIV = noninvasive ventilation; NMD = neuromuscular disease; OHS = obesity hypoventilation syndrome; ONMAP = Optimal NIV Medicare Access Promotion; PAP = positive airway pressure; PSG = polysomnogram; RAD = respiratory assist device; RCT = randomized controlled trial; S = spontaneous; S/T = spontaneous-timed; Tc_{CO_2} = transcutaneous measurement of PCO_2; TEP = Technical Expert Panel; TRD = thoracic restrictive disorder; VAPS = volume-assured pressure support; VBG = venous blood gas

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*A complete list of the ONMAP Technical Expert Panel members is presented in the Acknowledgments.

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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 this 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.

The treatment of hypercapnic ventilatory failure with nocturnal noninvasive ventilation (NIV) using portable positive airway pressure (PAP) therapy in the form of CPAP or bilevel positive airway pressure (BPAP) equipment or a home mechanical ventilator (HMV) has been occurring for decades. The use of BPAP therapy for patients with severe COPD and neuromuscular disease (NMD) became widespread during the 1990s. The Health Care Financing Administration (Centers for Medicare & Medicaid Services [CMS] precursor until 2001) would create a national coverage determination (NCD) policy for such durable medical equipment (DME), and policies would be managed locally by the DME Medicare administrative contractor (MAC) medical directors through local coverage determinations. These medical directors would become alarmed if outlays suddenly grew exponentially even when new technologies arrived in the marketplace.

In response to the meteoric rise in BPAP prescriptions and subsequent charges, the DME MAC medical directors implemented a regional medical review policy based on recommendations of a consensus conference of experts organized in 1998 by the American College of Chest Physicians and the National Association for Medical Direction of Respiratory Care to address NIV for patients with NMD, COPD, and other hypoventilation syndromes.[1] Today, technology development and best medical practice have outgrown these early policies and have left behind obstacles to current best care. We therefore initiated a patient-focused advocacy initiative to remove regulatory barriers for respiratory care patients called the Optimal NIV Medicare Access Promotion (ONMAP). Our mantra became one to ensure that "the right device gets to the right patient at the right time."

From the outset of the initial NIV NCD, a distinction was made between devices that were later defined by CMS as respiratory assist devices (RADs) and true ventilators. RADs were most easily recognized as hardware/software combinations providing positive pressure ventilatory support (BPAP) in response to a patient's effort (BPAP spontaneous [S] mode). In contrast, a true portable HMV offered considerably more features and was progressively more costly than the simpler RAD apparatus.

There were initially two categories of payment by CMS until a timed backup rate became available on some devices (BPAP spontaneous-timed [S/T] mode). CMS subsequently designated the RAD BPAP S/T device as a new intermediate reimbursement level RAD rather than a "ventilator" as it had been designated by the US Food and Drug Administration. All RAD CMS coverage would fall under the "capped rental" payment model with a fixed length of payment to the DME vendor until the CMS beneficiary would own the equipment. The HMV prescription, however, would require frequent and substantial servicing, and payment would continue for the life of the service and be accompanied by access to respiratory therapy services presumed necessary to manage more complex devices (CMS will correctly argue that the statute and regulations apply to frequent and substantial servicing for equipment, not professional services). Basing payment on the equipment description rather than clinical needs of the patient would prove progressively more confusing to physicians and patients. Beneficiaries were denied potentially lifesaving equipment given the rigid coverage criteria in local coverage determinations and the acknowledged lack of evidence-based support from clinical trials. The randomized controlled trial (RCT) research process is always slow and expensive, and although the standard of care for NIV did advance, much was determined by expert opinion in the form of societal consensus guidelines.[2,3]

The not-unexpected growth of Medicare payments following 2010 occurred when NIV support was prescribed as an HMV rather than a RAD for many posthospitalization patients with hypercapnic COPD. This coincided with the mandatory penalties for COPD readmission and might otherwise occur without NIV support. The Office of the Inspector General reported that

in 2009, Medicare paid 2,528 claims for HMV at a cost of $3.8 million, and in 2015 the agency paid 215,379 claims at a cost of $340 million.[4] The clinicians honestly stated that it was easier to prescribe HMV than a device with S/T mode capability. Clinicians also believed that the lifelong clinical/technical support accompanying the use of an HMV was crucial to successful use of NIV for a select patient population. CMS announced targeted increased denials and a plan to move HMV coverage into a competitive bidding category, thereby provoking deep concern from respiratory societies and patient advocacy groups.

Next came an Agency for Healthcare Research and Quality report on NIV in the home, leading to a comprehensive *JAMA* publication[5] describing the clear benefit of NIV in selected patients with hypercapnic COPD. This was followed by the Medicare Evidence Development Coverage Advisory Committee meeting that took place on July 22, 2020.[6] This meeting concluded with voting on crucial predetermined questions favoring use of high-intensity NIV in selected patients with hypercapnic COPD. More importantly, however, strong statements were voiced by many participants in favor of a comprehensive CMS review of all disease categories and a reconsideration of the current five NIV coverage criteria, including all bilevel devices[7] and those patients requiring NIV following unsuccessful CPAP therapy for OSA.[8] Direct discussion took place with the Coverage and Analysis Group shortly afterward, and their leadership acknowledged that they would be receptive to outside expertise as the basis for NCD reconsideration.

Methods

The most closely involved professional medical societies in the United States entered into a memorandum of understanding, including the American College of Chest Physicians (CHEST) as the lead organization, the American Academy of Sleep Medicine (AASM), the American Association for Respiratory Care, and the American Thoracic Society to develop and publish a Technical Expert Panel (TEP) report on recommendations for a revised NCD for the delivery of optimal NIV therapy to Medicare beneficiaries. The TEP report was to be seeded by an intense discussion of the issues during a 2-day video conference as described in the following sections.

Structure and Composition of the TEP

The TEP consisted of five separate committees focused on the following: (1) thoracic restrictive disorders (TRDs); (2) COPD; (3) central sleep apnea; (4) hypoventilation syndromes; and (5) CPAP and BPAP for OSA. The TEP chair was asked by the CHEST organizing committee to begin contact with physicians having experience in patient advocacy with previous upper-level administrative medical society positions and/or nationally recognized expertise. Each committee consisted of a chair, co-chair, and three members (see individual category documents for specifics). The committee co-chairs and members were selected after discussions with the TEP and committee chairs with consideration of balance from all four collaborating societies. All members of the TEP disclosed their potential conflicts of interest, which were vetted by the TEP chairs in accordance with the policies of CHEST (available at https://www.chestnet.org/-/media/chesnetorg/Guidelines-and-Resources/Documents/Guidelines-COI-Policy_Approved-January-2021.ashx).

Charge to Committees

Each committee was provided with the relevant current NCD and related policies and then charged with the task of identifying coverage gaps in conflict with vital new research, societal guidelines, or, when these were lacking, their collaborative clinical experience incorporating best evidence and practice together. All were asked to focus on CMS policy obstacles that delayed or denied optimal care for their patients. In categories where pertinent, specific attention was given to when patient needs required transition from a BPAP device to HMV support.

TEP Panel Meeting

All the work of the TEP was conducted by video teleconferences and electronic communications, and no face-to-face meetings were held because of existing COVID-19 pandemic safety concerns. Prior to the TEP virtual conference, weekly 1-h video conferences were held with the entire TEP during which each committee chair reported on their ideas for improvement related to their NCD and related policies. In addition, areas of mutual or overlapping concern were addressed and discussed to improve the efficiency of the TEP conference reports.

The virtual conference was held October 3 and 4, 2020. In addition to TEP members and support staff, the meeting was open to invited patient advocacy groups, industry partners, and DME providers, all of whom disclosed their affiliations. CMS was also invited and observed the meeting. A small number of these invitees were also granted 10 min each to present their perspective on the current NCDs and related policies. However, only TEP members participated in drafting the resulting commentary, conclusions, and suggestions from the meeting and for the NCD without any external influence or communication.

During the first day of the meeting, each committee presented 45-min talks on the "pain points" that prevented optimal patient care, followed by discussion moderated by the TEP co-chairs. On the second day, each committee presented initial suggestions to address these pain points, with another discussion following. The meeting and chat comments were recorded.

Drafting of Committee Reports and Executive Summary

After the TEP conference concluded, regular discussion within each committee took place, and an updated working draft was reported by the chair. Further fine-tuning took place over the next several months during near-weekly follow-up video conferences with all the TEP members. Numerous cycles of review and editing followed until all agreed that each statement was ready for final review by the entire TEP. All had the opportunity to review the other committees' reports, with additional comments and further edits shared as needed. The format of the reports was harmonized across all the

committees by the TEP co-chairs, who then created this Executive Summary. The Executive Summary was reviewed and approved by all TEP panelists. The Executive Summary and committee reports were reviewed and approved by CHEST and collaborating societies according to the memorandum of understanding and submitted to the editors of *CHEST* for a formal peer review process before subsequent planned NCD submission. The report of the five categories that follows is the nisus from a selection of the nation's most recognized NIV experts and finally producing these suggestions for this ONMAP, which singularly focused on improving policies that will match a patient's clinical needs with the appropriate device when they need it.

Thoracic Restrictive Disorders

The TRDs included here have ventilatory defects and subsequent NIV need due to NMDs, chest wall deformity, and other defects in generation of respiratory drive. This category does not actually require demonstration of restrictive pulmonary function parameters and specifically excludes even those with profound restriction from interstitial lung disease.

The current NCD and related coverage policies outline criteria that require an appropriate TRD diagnosis and most often include mild hypercapnia $\geq$ 45 mm Hg, although this indication identifies already significantly advanced disease (Fig 1). Use of stringent alternative spirometry and oximetry qualifying criteria may inhibit timely NIV therapy to those symptomatic patients with shortness of breath because symptoms are not accepted as a determinant of coverage. The additional barriers involved are related to the challenging travel needed to obtain laboratory measurements for these patients who are commonly debilitated with progressive NMDs (amyotrophic lateral sclerosis, muscular dystrophy, and diaphragm paralysis). The TRD TEP consultants proposed solutions for delays in NIV treatment advising consideration of breathlessness with even mild reduction in vital capacity and easier and less costly alternative testing for hypercapnia (Table 1) and then provided justifications for these suggestions.

Canadian and German respiratory societies have published guidelines endorsing similar reductions in vital capacity and symptoms of breathlessness as inclusion criteria for earlier introduction of NIV.[9,10] Future criteria also need to provide coverage for nonprogressive NMD including (but not limited to) phrenic nerve injury, spinal cord injury, cerebral palsy, multiple sclerosis, and spina bifida and congenital central hypoventilation syndrome, with a more comprehensive list provided in the TRD section details.

The TRD and hypoventilation syndromes categories emphasize the need to accept alternative measurements of hypercapnia because arterial blood gas (ABG) sampling is the only measure currently recognized by the CMS policies for measurement of gas exchange. Venous blood gas (VBG) sampling is cheaper, easier, and less uncomfortable for the patient, and end-tidal CO_2 (Et_{CO_2}) and transcutaneous CO_2 (Tc_{CO_2}) are measures that have been used successfully as surrogates for Pa_{CO_2}. The VBGs parallel ABG values well but generally exceed the Pa_{CO_2} value by approximately 5 mm, and the TEP suggestions in Table 1 and other categories take this into account.[11] The Tc_{CO_2} and Et_{CO_2} measurements also track ABG results closely and are more commonly available in sleep laboratories.

A major defect for current policies is the failure to clearly identify the patient phenotype that requires either initial or transition to the use of NIV with HMV therapy. It was apparent within the TEP panel that in most cases, a BPAP device was the preferred device and HMV treatment is reserved for patients with advanced and severe chronic respiratory failure, usually progressive or with a recent exacerbation. As within

Any single criterion sufficient to initiate BPAP device in TRD
1. Symptoms plus a VC < 80%
   - ✓ Orthopnea, dyspnea, morning headache, daytime sleepiness, or unrefreshing sleep
2. CO_2 measurement
   - ✓ Daytime/awake ABG $Paco_2 \geq$ 45 mm Hg
   - ✓ $Etco_2$/$Tcco_2$ or VBG $CO_2 \geq$ 50 mm Hg
3. Sleep-related oxygen saturation from any source, including PSG/HST
   - ✓ ≤ 90% for ≥ 5% of the night
   - ✓ ≤ 88% ≥ 5 min
4. VC (either FVC or slow VC)
   - ✓ ≤ 50% predicted
5. MIP/SNIP- is less negative then the values below
   - ✓ MIP ≤ –60 cm H_2O (equal or worse than)
   - ✓ SNIP ≤ –40 cm H_2O (equal or worse than)

Figure 1 – *Criteria sufficient to initiate BPAP device in TRDs. ABG = arterial blood gas; BPAP = bilevel positive airway pressure; HST = home sleep test; MIP = maximal inspiratory pressure; PSG = polysomnogram; SNIP = sniff nasal inspiratory pressure; TRD = thoracic restrictive disorders; VBG = venous blood gas; VC = vital capacity.*

each TEP category, the clinicians identified the severe patients notable "when they walked into the room," and all could recognize and describe them clearly enough to secure HMV coverage.

The patient with TRD and progressive NMD provides such an easily recognizable situation for HMV equipment coverage. When a patient develops the need for prolonged ventilatory support (> 10 h per day) or daytime support such as with a mouthpiece-ventilator interface, the patients with TRD are end-stage NMD and need HMV. This allows accompanying battery backup for sudden power loss and greater mobility and independence on a motorized wheelchair. Once the patient requires HMV for >18 h per day, ventilator dependency is confirmed, and a second device for safety and mobility is prescribed when determined to be medically necessary by the treating physician. The proposed criteria and treatment pathways for patients with TRD are detailed in the TRD TEP report accompanying this summary.

Summary of Suggested Changes

We propose that an updated CMS NCD policy for NIV in TRD incorporate a clear pathway for coverage of HMV, as noted in Figure 2.

COPD

When BPAP therapy was introduced, the Health Care Financing Administration viewed NIV as an alternative or supplemental therapy for patients with severe hypercapnic COPD failing oxygen therapy and, thus, included failed overnight oximetry criteria as determinants for coverage. This is not a physiologically sound pathway because, first, oxygen supplementation during sleep will cloak $Paco_2$ levels and promote further hypoventilation, and nocturnal normoxemia can be ongoing and even more progressive, especially with severe hypercapnic conditions.[12] Physicians readily know that supplemental oxygen can worsen existing hypercapnia by altering $\dot{V}/\dot{Q}$ interactions and blunting the sluggish hypoxic drive in these patients.

Second, no clinical trials of patients with severe hypercapnic COPD investigating NIV therapy have used this criterion for inclusion, and thus there was no scientific evidence to support use of this mandatory oximetry criteria. Patients with significant ventilatory failure in need of NIV can be denied therapy, and therefore this qualifying criterion should be abandoned. The COPD TEP members advised removal of the requirement for a "nocturnal oximetry study using either 2 LPM [L/min] nasal O_2 or the patient's usual Fio_2, whichever is higher."

Since the current guidelines were created, crucial evidence has accrued, and it is urgent that we critically re-examine the NCD and corollary policies and advise alterations that will facilitate delivery of clinically appropriate therapy. Previously, the primary outcome goal of the COPD RCTs was a reduction in $Paco_2$ while

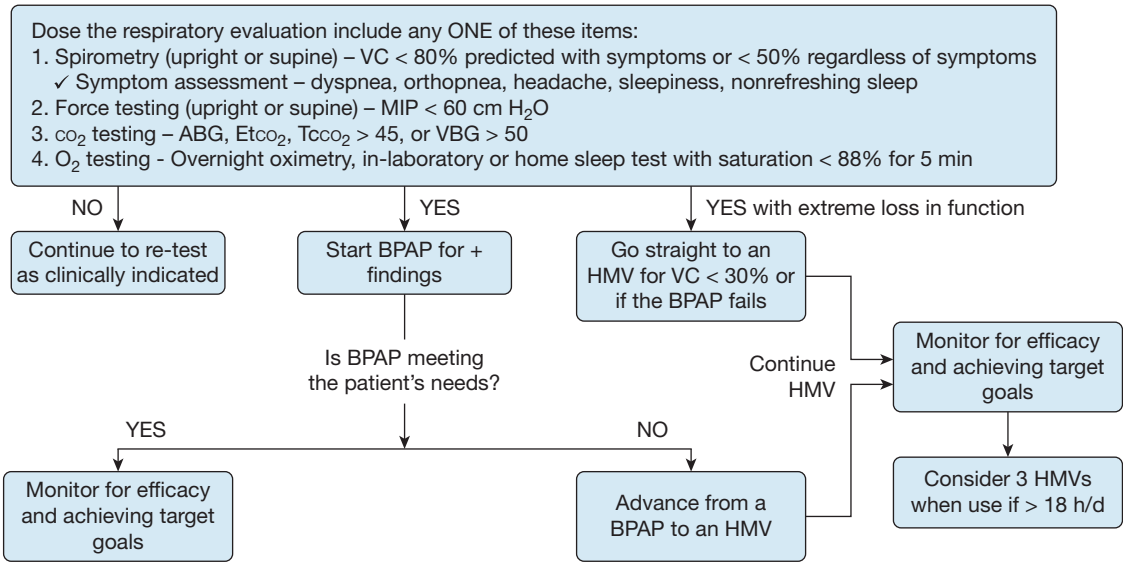


Figure 2 – *Suggested initiation and monitoring of noninvasive ventilation therapy in thoracic restrictive disorders. ABG = arterial blood gas; BPAP = bilevel positive airway pressure; $Etco_2$ = end-tidal measurement of PCO_2; HMV = home mechanical ventilator; MIP = maximal inspiratory pressure; O_2 = oxygen; $Tcco_2$ = transcutaneous measurement of PCO_2; VBG = venous blood gas; VC = vital capacity.*

TABLE 1] Suggested Changes to the Current Coverage Determination for CSA

• A single definition of CSA will simplify and clarify coverage decisions
• The discussion of CSA should not refer to hypoventilation
• Qualifying symptoms for CSA therapy should be the same symptoms that qualify a patient for OSA therapy
• All effective therapies for CSA should be covered by CMS. CPAP, BPAP, and PAP devices with a back-up rate (ie, E0471 [including BPAP S/T, servoventilation, and volume-assured pressure support]) and oxygen are effective for select patients
• Patients with CSA frequently need E0471 therapy. Coverage of E0471 for these patients should not require prior failure of BPAP without a backup rate. Patients with suboptimal response with one E0471 device should be allowed to switch to a different E0471 device if shown to be effective with testing
• The requirements for continuing coverage for CSA therapy should be the same as for continuing coverage of OSA therapy

BPAP = bilevel positive airway pressure; CMS = Centers for Medicaid & Medicare Services; CSA = central sleep apnea; PAP = positive airway pressure; S/T = spontaneous/timed.

awake, and there was but a single RCT in 1995 showing such a successful benefit for NIV in patients with severe stable COPD.[13] The success was accomplished with an S mode BPAP device without a backup rate; based on those data, NIV was approved for use in Medicare patients with hypercapnic COPD. The $Paco_2$ level of 52 mm Hg was somewhat arbitrarily chosen by the DME MAC medical directors as the lower range of enrolled patients (range, 52-65 mm Hg), whereas other concurrent studies were conflicting.[14] The older scientific literature to support the prevailing clinical NIV practice of the time was scant, leading to a difficult and somewhat capricious choice of the original coverage criteria of overnight oximetry, $Paco_2 \geq 52$ mm Hg, and an allowance for only an S mode BPAP.

There were few changes to the COPD coverage criteria for the next three decades despite the 2014 landmark multicenter RCT of BPAP S/T or HMV in this type of patient with COPD and resting $Paco_2$ of ≥ 52 mm Hg.[15] The primary outcome was striking, with a new gold standard end point showing a 36% relative reduction in 1-year all-cause mortality (12% NIV vs 33% control subjects), and a similar benefit was retrospectively confirmed by using the Medicare Limited Data Set (2012-2018).[16] As noted previously in the Agency for Healthcare Research Quality report of NIV in the home, for COPD, BPAP S/T reduced dyspnea and mortality and increased activities of daily living, whereas both BPAP S/T and HMV reduced hospitalizations.[5] In other guidelines, a European Respiratory Society Task Force in 2019 and an American Thoracic Society subcommittee in 2020 both suggested reduced mortality or rehospitalization using home NIV for patients with stable hypercapnic COPD following hospitalization for an exacerbation.[3,17]

The COPD TEP group concluded that coverage criteria for patients with severe COPD should be replaced with the following criteria:

1. ABG while awake and receiving supplemental oxygen (if prescribed), demonstrating a $Paco_2 \geq 52$ mm Hg; and
2. OSA and CPAP treatment have been considered and ruled out (formal testing not required; this only requires clinical documentation).

The COPD TEP group also identified the most severe COPD patient phenotype that any should be considered for an HMV when the treating physician determines need for:

- Higher pressures than those deliverable by E0471
- Fio_2 higher than 40% or 5 L/min nasally, which is greater than can be supplied by E0471
- 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

Summary of New Suggested Changes

The flow diagram presented in Figure 3 summarizes our advised requirements for coverage of BPAP and HMV in patients with COPD and chronic hypercapnic respiratory failure. We advocate persistent hypercapnia as the main determinant of candidacy without the requirement for a 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.

Additional Considerations

Respiratory Therapy Support Services: The COPD as well as the TRD category and the hypoventilation syndromes TEP felt strongly that both evidence and consensus opinion support the necessity of ongoing clinical/technical support for these patients.[5] The TEP groups fully recognize that the Medicare DME benefit

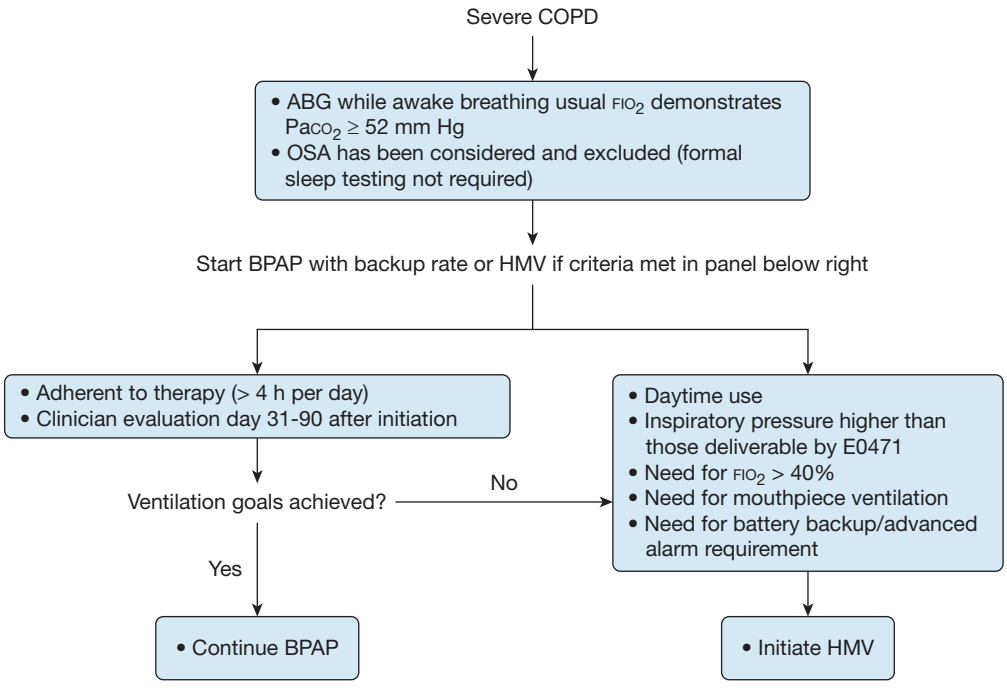


Figure 3 – *Suggested management of patients with COPD who require noninvasive ventilation. ABG = arterial blood gas; BPAP = bilevel positive airway pressure; HMV = home mechanical ventilator.*

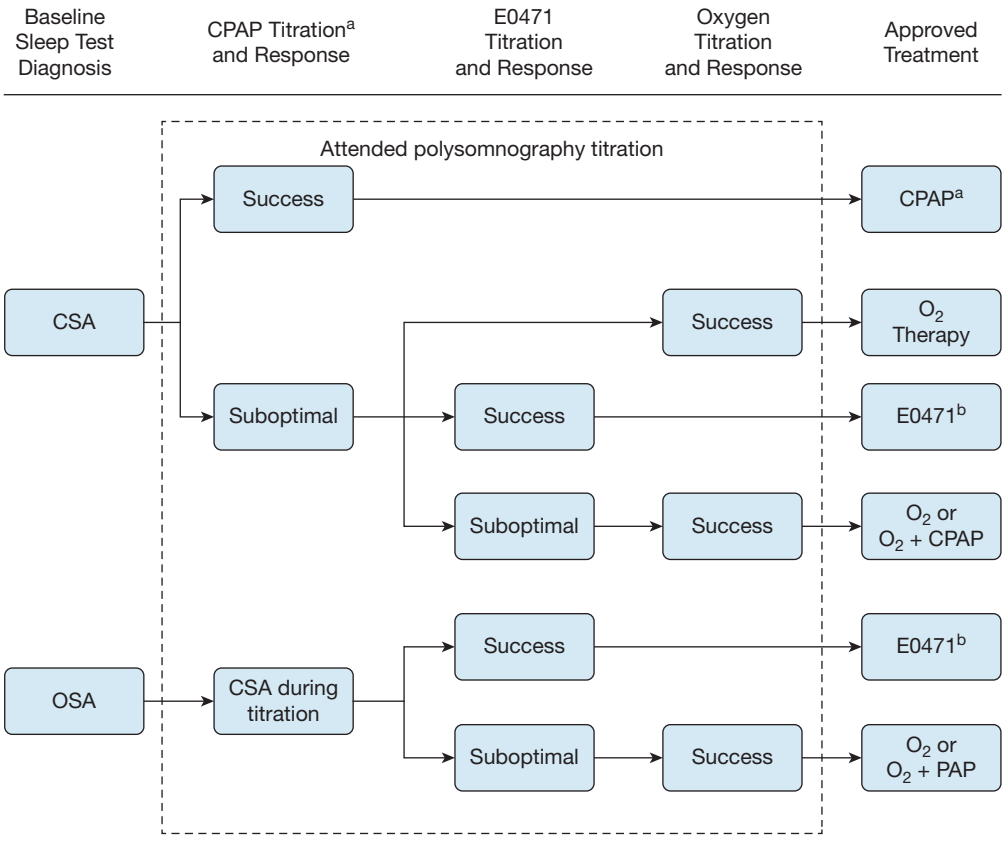
provides coverage and payment for equipment and not professional services in the form of clinical support for NIV patients. Patient services are a separate billable service, but it is a recognizable expectation that complex equipment may itself require "frequent and substantial servicing" from a respiratory therapist and deserves a higher perpetual payment. The clinical specialists believe that such services are essential for initiation of advanced NIV therapy, and without ongoing support, patients are at risk for ineffective device performance and poor outcomes. This level of support is the standard of care and a common clinical practice; was provided in all of the clinical trials supporting NIV use for COPD; and is the standard of care in most European NIV programs.[14] We will need to devise a pathway in the future, and we strongly advocate for visits to provide these necessary skilled respiratory therapy services in the home for patients with advanced NIV and all types of severe chronic respiratory failure if we are to achieve optimal NIV Medicare access.

Central Sleep Apnea

The central sleep apnea (CSA) TEP identified current ONMAP barriers and were concerned about qualifying coverage language details in the current NCD and related policies. They then wanted to address policies that currently deny CPAP devices and/or oxygen therapy that provide clinical benefit. The qualifying language issues regarding symptoms for CSA therapy described at some length in the current NCD are rarely documented by physicians and should be rewritten and generalized to parallel qualifying issues for OSA therapy. This will lead to a reduction in unnecessary denials.

The panel further advised that the coverage policies adopt a single definition of CSA that aligns with accepted definitions, with CSA predominance. The current language includes an obstacle of necessitating resolution of nearly all obstructive events prior to allowing treatment for CSA and should be removed. Finally, although for a minority of patients, CPAP and/or oxygen provide significant improvement in CSA, and the revised policies should allow therapy based on best current practices and recommended in AASM clinical guidelines.[18]

A simplified evaluation pathway is presented to appropriately guide clinicians who need to provide therapy for CSA and accommodates those patients with an initial diagnosis of CSA or those who begin with OSA and develop treatment-emergent CSA. The patient initially diagnosed with either OSA or CPAP when first exposed to CPAP would occasionally declare benefit from CPAP alone or proceed to further titration with an E0471. This opens access for the small population of patients with CSA who benefit from an E0601 who are presently denied despite it being a first-line recommendation in the AASM guidelines (Fig 4).



Suboptimal responses to CPAP or E0471 must be demonstrated by attended polysomnography. Titration of CPAP, E0471, and/or O_2 may be done during single in-laboratory study as time allows.
[a]A BPAP S made be used instead of CPAP, although this usually has worse results than CPAP.
[b]The patient's medical condition may preclude acceptability of E0471 therapies, in which case other treatments should be considered. It may also be necessary to add O_2 to E0471 in some cases.

Figure 4 – *Advised evaluation and treatment pathway for CSA. CSA = central sleep apnea; O_2 = oxygen; PAP = positive airway pressure.*

An additional therapeutic problem exists regarding the follow-up for patients with CSA requiring E0471 devices; these patients are currently required to have a face-to-face follow-up in 61 to 90 days after the start of therapy even if documentation of adherence and benefit can be made earlier in the first month. There is no clinical reason why delayed evaluation is necessary for this population.

Summary of New Suggested Changes

The policy providing continuing coverage for CSA should include the same criteria as patients with OSA and clinical documentation of benefit can be shown in the same 31 to 90 days as CPAP. However, consistent with the other TEP category suggestions, those still engaged with their NIV treating physician and not yet meeting adherence criteria at day 90 should be allowed coverage for another 90-day period prior to consideration of alternative therapy.

A detailed summary of suggested changes in the current coverage determinations, which will improve care for patients with CSA, is listed in Table 1.

Hypoventilation Syndromes

Hypoventilation syndromes refer to a heterogeneous group of disorders characterized by hypercapnia, defined as $Paco_2 > 45$ mm Hg not explained by another category. Many hypoventilatory syndromes with hypercapnia are included in this category such as those caused by obesity (BMI $\geq$ 30 kg/m^2; eg, obesity hypoventilation syndrome [OHS]), central respiratory drive depression associated with medication or substance use (eg, opioids), and decompensated hypercapnic respiratory failure other than COPD such as end-stage interstitial lung disease.

Hypoventilation frequently complicates severe obesity among hospitalized adults, and it is associated with

excess mortality and increased readmissions. The American Thoracic Society published clinical guidelines recommending that hospitalized patients with respiratory failure suspected of having OHS be started on NIV therapy, prior to discharge from the hospital, until they undergo outpatient workup and titration of PAP therapy in the sleep laboratory within the first 3 months following hospital discharge.[3] Like the COPD TEP, the hypoventilation syndromes TEP advised that all initial BPAP S mode qualifying criteria should be abandoned and direct BPAP S/T access enabled. Thus, the TEP advises that, ideally, clinicians are able to use BPAP S/T with empiric settings or autotitrating NIV such as volume-assured pressure support (VAPS) with the auto-expiratory positive airway pressure (EPAP) feature, which has the capability to automatically adjust the respiratory rate to treat hypoventilation; in addition, the auto-EPAP feature can ensure upper airway patency in case of increased resistance (eg, OSA).

The hypoventilation syndromes TEP members urged inclusion of several "orphan" hypoventilation diagnoses and adoption of a simplified pathway to coverage presently so problematic that it is the least useful to clinicians. As with the TRD TEP and the COPD TEP, the hypoventilation syndromes TEP members also suggest adoption of alternatives to exclusive ABG testing for qualification in favor of the less uncomfortable and noninvasive $Etco_2$ or $Tcco_2$. Their specific suggestions are given in the following section.

Summary of New Suggested Changes

The current clinical suggestions for NIV are indicated for hypoventilation syndromes (Fig 5), as defined by an elevated Pco_2 in arterial or venous blood, $Tcco_2$, and $Etco_2$.

Coverage in the hypoventilation syndromes category includes the following clinical conditions:

A. OHS (eg, E66.2).
B. Hypoventilation due to central respiratory drive depression associated with medication, substance use, or other medical conditions (eg, opioids F19.982, G37.46; neurogenic R06.89; medical condition G47.36).
C. Hypoventilation due to respiratory system disease *other than COPD* (eg, end-stage interstitial lung disease, J98.4, G47.36), neuromuscular diseases, or thoracic cage disorders, which are covered elsewhere.

Suggested Changes for Outpatient NIV Support for Hypoventilation Syndromes

A. Obesity hypoventilation syndrome
- Hospitalized patients with persistent awake hypoventilation at the time of discharge following an episode of hypercapnic respiratory failure (J96.22: Acute and chronic respiratory failure with hypercapnia) should trial BPAP ventilation *with* backup rate (BPAP S/T or VAPS [E0471])
  - For ongoing coverage of equipment, a reassessment with a qualified practitioner within 3 months is required and an attended polysomnogram (PSG) should be performed to assess appropriateness of PAP modality
  - Unattended type II/III/IV portable sleep apnea testing (home sleep apnea test) is not advised in patients with hypoventilation but is acceptable if attended PSG is not obtainable
- Ambulatory obese patients with awake or sleep-related hypoventilation and without severe OSA (defined as an apnea-hypopnea index or respiratory disturbance index < 30 events/h), ideally

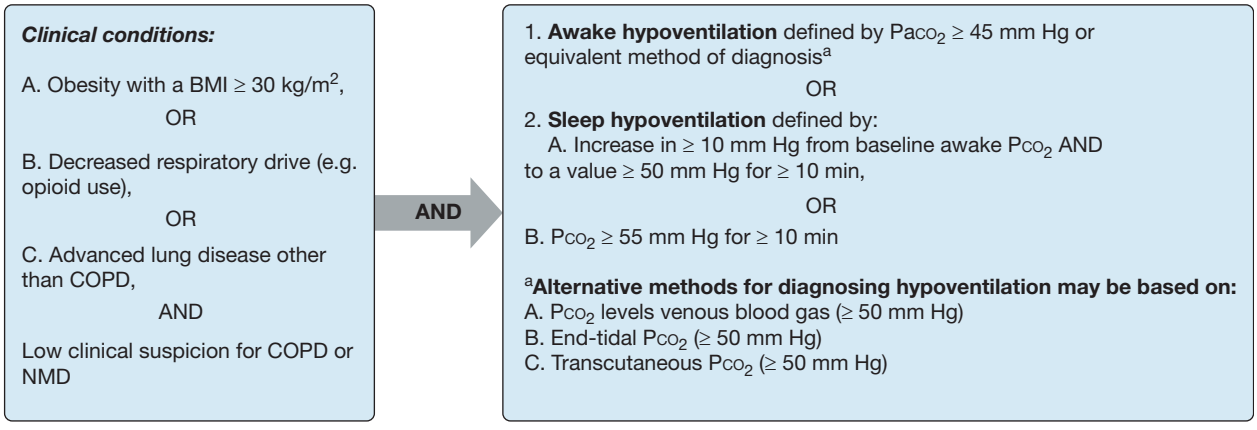


Figure 5 – *Suggestions for the definition of clinical conditions related to hypoventilation syndromes. NMD = neuromuscular disease.*

based on an attended PSG, should be started on BPAP S/T or VAPS (E0471)
    - For ongoing coverage of equipment, a follow-up with a qualified practitioner within 3 months is required to assess response to therapy and assess appropriateness of PAP modality
        - A home sleep test is not advised in patients with hypoventilation but is acceptable for the diagnosis of OSA if attended PSG is not readily obtainable
- Ambulatory obese patients with wake or sleep-related hypoventilation and with severe OSA (defined as an apnea-hypopnea index or respiratory disturbance index ≥ 30 events/h), based on attended PSG or home sleep test, should be started on CPAP or auto-CPAP therapy (E0601)
    - Patients who are intolerant or proven ineffective with CPAP may engage the protocol advised by the "Failed CPAP for OSA" TEP
    - If the patient with OHS remains hypercapnic (awake $Paco_2$ ≥ 45 mm Hg, or PCO_2 ≥ 50 mm Hg on VBG, $Etco_2$, or $Tcco_2$ despite adequate adherence to CPAP (E0601) or BPAP S (E0470) after 3 months, a BPAP S/T (E0471) may be considered without need for repeat sleep testing

B. Ambulatory patients with hypoventilation due to central respiratory drive depression associated with medication, substance use, or other medical conditions (eg, opioids) may be considered for BPAP S/T or VAPS (E0471) without the need of sleep testing
    - Sleep testing may be considered if concomitant sleep apnea is suspected, or for titration of NIV

C. Hypoventilation due to respiratory system failure other than COPD or NMD/thoracic cage disorder (eg, end-stage or advanced interstitial lung disease) should be considered for: BPAP S/T or VAPS without the need of sleep testing
    - Sleep testing may be considered if concomitant sleep apnea is suspected, or for titration of NIV

NIV via an HMV (E0466) is advised for patients with hypoventilation who need any of the following:

- Higher pressures than those deliverable by E0471
- Fio_2 > 40%, which is greater than can be supplied to an E0471
- Need for bilevel modes with autoadjusting EPAP capability (only if not available in any E0471 device) in patients with hypoventilation syndromes when the presence and/or severity of OSA is unknown at the time of device prescription
- Need for daytime ventilation or > 10 h per day
- Severe disease that requires a device with batteries or alarms, or requires a backup ventilator, or inability to apply or disengage mask without assistance. Severe disease was defined as a history of ≥ 2 hospitalizations for hypercapnic respiratory failure (J96.02), OR persistent hypercapnia as defined by $Paco_2$ ≥ 45 mm Hg (or surrogate Pco_2 measurements ≥ 50 mm Hg) despite adequate adherence to BPAP S/T therapy

The suggested management pathway is as shown in Figure 6.

Supplemental oxygen therapy suggestions with NIV

- Oxygen supplementation should be adequate to achieve an oxygen saturation by pulse oximetry 88% to 92% in all causes of chronic hypercapnic respiratory failure following achievement of optimization targets of NIV settings as determined by the treating physician

CPAP and BPAP Therapy for OSA

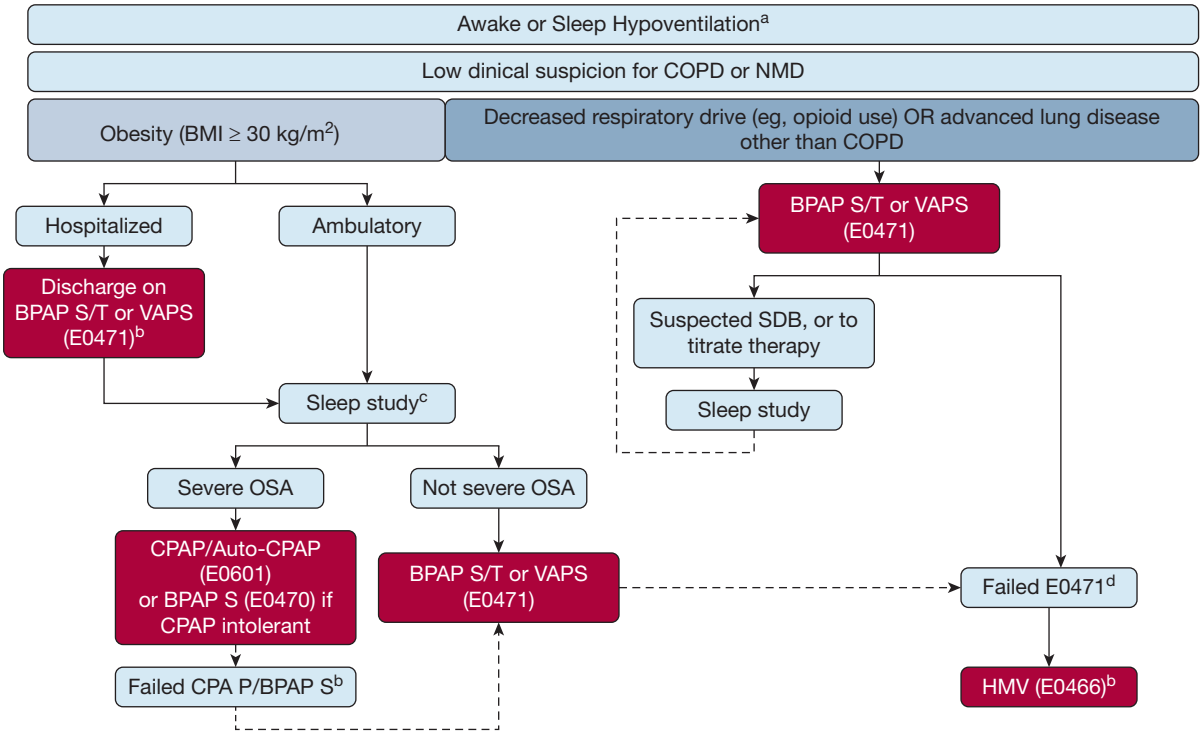
The current policies[8] for OSA allow coverage for PAP therapy for Medicare beneficiaries with mild OSA only if specific symptoms are initially present for CPAP use. The use of BPAP in such appropriately symptomatic patients with OSA is then an allowable option when CPAP "has been tried and proven intolerable or ineffective." Many patients with mild OSA experience unlisted OSA-related symptoms such as nocturia or morning headache that adversely impair their quality of life when CPAP is not covered. The revised coverage determination policy regarding symptom(s) should be stated by the treating physician but not restricted to a specified list for beneficiaries with mild OSA for initial coverage of a PAP device (E0601 or E0470).

Based on the report from the data reviewed and consensus conclusions provided in the "Ineffective CPAP" committee, several other suggestions for a revised NCD and related policies are continued in the following sections and are highlighted in Figure 7.

Summary of Suggested Changes

Definition of symptomatic patients with OSA

- The revised coverage determination policy regarding symptoms should be the same as beneficiaries with mild OSA for initial coverage of a PAP device (E0601 or E0470) and should be revised to allow coverage for:



[a] **Awake hypoventilation** defined by $Paco_2 \geq 45$ mm Hg or equivalent method of diagnosis, OR **Sleep hypoventilation** defined by ≥ 10 mm Hg increase from baseline awake Pco_2, AND to a value ≥ 50 mm Hg for ≥ 10 min, OR $Pco_2 \geq 55$ mm Hg for ≥ 10 min. (Alternative methods for diagnosing hypoventilation may be based on venous blood gas, end-tidal co_2, or transcutaneous $co_2 \geq 50$ mm Hg.).
[b] In certain circumstances, patients may need to be discharged from the hospital on VAPS-AE or HMV or may require HMV without having failed BPAP S/T or VAPS (see text for summary of new suggestions).
[c] For ongoing coverage of E0471 following hospital discharge, a reassessment with a provider within 3 months is required and a sleep study should be performed to assess appropriateness of PAP modality.
[d] Therapy failure defined as persistent hypercapnia or symptoms following 3 months of adequate adherence to prescribed PAP therapy.

Figure 6 – *Suggested management pathway of patients with hypoventilation. BPAP = bilevel positive airway pressure; CMS = Centers for Medicare & Medicaid Services; HMV = home mechanical ventilator; NMD = neuromuscular disease; PAP = positive airway pressure; S = spontaneous; SDB = sleep-disordered breathing; S/T = spontaneous/timed; VAPS = volume-assured pressure support.*

1. Any impairment in sleep-related quality of life that in the judgment of the treating physician may be expected to benefit from therapy.
2. Comorbid cardiovascular conditions (eg, hypertension, diabetes, ischemic heart disease, history of stroke).

BPAP for patients intolerant of CPAP

- The "tried and proven ineffective" language concept could be preserved.

Policy for continued coverage

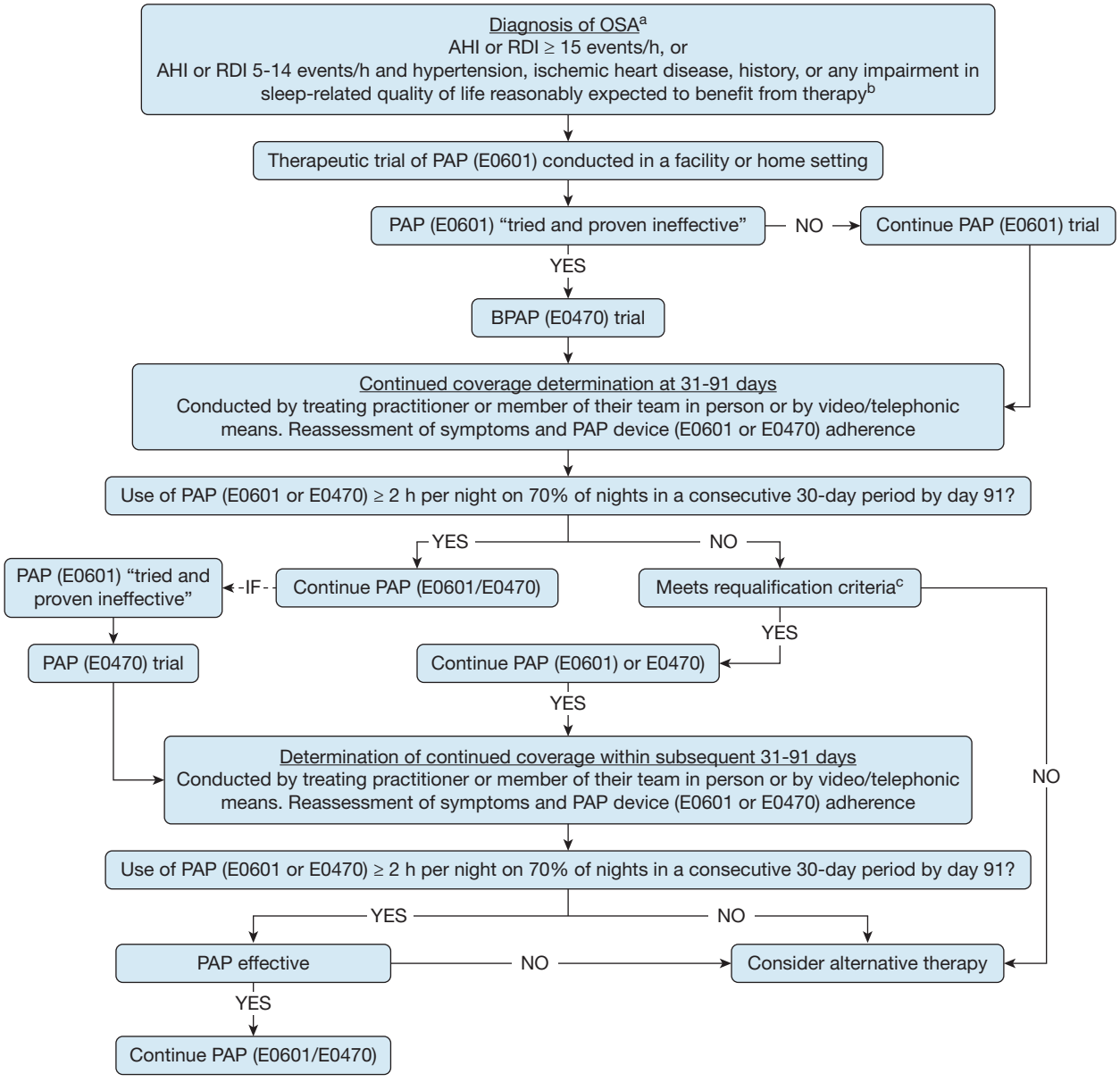
- The treating practitioner (or designee) conducts a clinical re-evaluation and documents that the beneficiary is using and benefiting from PAP therapy.
- The clinical re-evaluation can be performed either by the treating practitioner or members of their health care team within their scope of their clinical practice.
- Objective adherence to the use of PAP device based on utilization data should be reviewed and documented by the treating practitioner.
- Adherence to therapy should be considered acceptable with PAP ≥2 h per night on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial usage. If use and/or benefits have not been reached by day 91, the beneficiary must requalify.

Requalification for PAP

- The need for additional sleep testing should be at the discretion of the treating practitioner, rather than a requirement, and may be either home or facility based.

Concurrent oxygen with PAP

- Although the TEP recognizes that concurrent use of oxygen with PAP may be outside the coverage determination policy for BPAP, it is important to comment on potential revisions needed given the wide regional variation in implementation of current policies by the DME MACs and DME suppliers, and details are provided in the parent document.[19]



[a]if patient is new to CMS and prior sleep-related quality does not available: Beneficiary eligible for PAP coverage if treating practitioner conducts a clinical-evaluation within 6 months of an order for a replacement PAP device or supplies and documents that the benefitting from PAP therapy based on meeting adherence criteria and improvements in OSA-related symptoms

[b]Examples of impaired sleep related quality life that may be expected to benefit from PAP include but are not limited to decreased energy or vitality, excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, nocturia, sleep-related choking, awakening headaches, reduced productivity, or impaired social functioning

[c]Treating practitioner/team evaluates etiology of PAP failure, implements troubleshooting and behavioral interventions as needed, considers alternative diagnoses, and orders additional testing as needed

E0601 = Continuous positive airway pressure and automatic positive airway pressure
E0470 = Bilevel positive airway pressure therapy limited to patient initiated breaths

Figure 7 – *Proposed treatment with CPAP and BPAP for patients with OSA. AHI = apnea-hypopnea index; BPAP = bilevel positive airway pressure; PAP = positive airway pressure; RDI = respiratory disturbance index.*

Telehealth Provision

- Re-evaluations for CMS beneficiaries with OSA required following initiation of PAP therapy may be accomplished by either in-person or video/telephonic means.

Conclusions

From the initial efforts beginning following the July 2020 Medicare Evidence Development Coverage Advisory Committee meeting, to the submission of this complete report in February 2021, exceptionally qualified expert clinician/researchers came together quickly without compensation and committed immense effort to this pioneer process. It has been stated that "ontogeny recapitulates phylogeny" and perhaps so should technology recapitulate pathology. Technology in this arena, however, has taken off in such a quantum fashion that it assumed its own trajectory. The existing pathway was lacking the rigorous scientific support necessary to clarify the "reasonable and necessary" role in each of these new mechanical therapeutic modalities, some of which, being the standard of care, led to conflicts producing arbitrary barriers to the delivery of optimal care. What was clear was the need to simplify the maze of regulation and, perhaps most importantly, remove the obstacles surrounding the coverage policies for the BPAP backup rate that obstruct reasonable decision-making, which should be the purview of the clinician. The use of HMV should be judicious and appropriate when the need is specifically identified and clinically supported.

We must be clear that our suggestions do not represent guidelines in the traditional sense of a professional societal publication. This evaluation was designed to provide the Coverage and Analysis Group an up-to-date awareness of the "state of the art" clinical practice from the best expert consensus available. CMS clearly stated to us that they would typically need to seek outside technical expertise to address these complex and intertwined clinical scenarios, and they would welcome the information provided from evidence clarification by this TEP. We believed that was a pronouncement to guide us all through the long overdue comprehensive revision of the NCD and related policies for NIV. This report is structured within the rules governing the NCD reconsideration process, and thus broad opportunity for public comment is expected when our appropriately formatted NCD document will be submitted after all of our documents were accepted for peer-reviewed publication in *CHEST*. We do believe, however, that we have provided a positive impact for an ONMAP for patients and hope this may open a door for future exchange between the clinical experts and CMS policy makers. A formal NCD reconsideration request will be forthcoming from the supporting previously noted medical societies.

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%7CKey%7CSAD%7CFAQ&PolicyType=Final&s=5%7C6%7C66%7C67%7C9%7C38%7C63%7C41%7C64%7C65%7C44&KeyWord=Home+Oxygen&KeyWordLookUp=Doc&KeyWordSearchType=And&kq=true&bc=IAAAABAAAAAA&

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