Submitted electronically to: NCDRequest@cms.hhs.gov

September 9, 2021

Ms. Tamara Syrek Jensen
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Formal Request for Reconsideration of §280.1, Durable Medical Equipment Reference List: Ventilators, Pub 100-03, Part 4, Chapter 1**

Dear Ms. Syrek Jensen:

This is a formal reconsideration request to revise §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 and to replace in its entirety the reconsideration request for Ventilators for Chronic Obstructive Pulmonary Disease (COPD) identified on CMS' Wait List Dashboard and originally submitted on March 25, 2016.

In conjunction with procedures established by the Centers for Medicaid & Medicare Services, this request is made by 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.

The TEP, convened with the tacit encouragement of the Coverage and Analysis Group (CAG), was designed to address various segments of the respiratory patient population who can benefit from noninvasive ventilation. The panel identified the standards of care related to device selection for specific patient populations and the peer-reviewed literature supporting these approaches to care. The segmented patient populations include:

1. Chronic Obstructive Pulmonary Disease
2. Thoracic Restrictive Disease
3. Hypoventilation Syndromes
4. Central Sleep Apnea

5. Obstructive Sleep Apnea

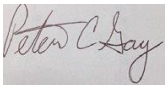
The recommendations included in this request impact policies beyond the cited NCD, particularly NCDs related to Home Use of Oxygen (§240.2) and Continuous Positive Airway Pressure for Obstructive Sleep Apnea (§240.4). Pursuant to discussions with staff from the CAG, this overlap of the NCD for ventilators and related local coverage policies is recognized and acknowledged by the respective societies as well as CAG staff; therefore, this request should not be considered as a limited request to focus solely on the current NCD §280.1 identified above.

The TEP consisted of clinicians from each of the four organizations noted above with expertise in the clinical conditions and treatment modalities of these patient populations. The final product of the TEP, designed to ensure the patient gets the right device for the right reason at the right time, consists of an Executive Summary that includes an outline of the structure and composition of the TEP, the process for development of the panel's recommendations, and a series of clinical manuscripts, the latter of which comprise this NCD reconsideration request. These documents are available online in the peer-reviewed journal, *CHEST*. A list of the participants and their institutional affiliations is attached for your convenience.

For each of the five major categories noted above, this letter and the accompanying attachments: 1) identify current coverage policies regarding noninvasive ventilators, including those that provide bilevel positive airway pressure support (BPAP) with or without backup and continuous positive airway pressure (CPAP); 2) discuss problems with current coverage policies; 3) make recommendations for amending these policies; and 4) provide clinical evidence and justifications with peer-reviewed citations to support the recommendations.

On behalf of the TEP, and with the full support of the four contributing organizations that collectively represent the vast majority of caregivers of the pertinent Medicare patient population, we are pleased to submit this NCD reconsideration request and welcome the opportunity to further discuss any of the evidence supporting the request or to clarify our recommendations as well as answer any questions CAG might have. Please feel free to contact Peter Gay at pgay@mayo.edu or 507-261-1032.

Sincerely,



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Formal Request for National Coverage Determination Reconsideration Request

Noninvasive Mechanical Ventilation

I. INTRODUCTION

The pulmonary community has previously discussed the need to improve coverage rules related to noninvasive home mechanical ventilation (HMV) across a spectrum of policies related to various patient populations dating back to 2014. We have had a long history of working with the Centers for Medicare & Medicaid Services (CMS) central office staff in the Coverage and Analysis Group (CAG) as well as the Durable Medical Equipment Medicare Administrative Contractors (DMEMACs) to update policies, bringing us to the current request.

To assist CAG in its review, it is important to acknowledge three key activities over the past year that have shaped our recommendations. First, at the request of CMS, the Agency for Healthcare Research and Quality conducted a technology assessment to evaluate home noninvasive positive pressure ventilation in adults with chronic respiratory failure. Second, the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) hosted a forum for discussion/review of the issues raised that are integral to this request. Third, as a result of the MEDCAC process, it became important that the respective societies host its own Technical Expert Panel (TEP) to address in detail these clinical coverage policies, recognizing that the technologies associated with HMVs, bilevel positive airway pressure (BPAP) devices, and CPAP devices have not only changed but their respective applicability to a range of clinical scenarios has changed as peer-reviewed evidence has improved the care of the patients who benefit from use of these devices.

Additional Considerations

One of the major frustrations encountered by the clinical community is broad confusion over certain terms used by the Food and Drug Administration (FDA) and CMS, sister agencies under the umbrella of the Department of Health and Human Services. CMS has generally not accepted the FDA classification of certain devices as “ventilators.” It has also created the term “respiratory assist devices” (RADs) for administrative and payment purposes, exacerbating confusion among the broad pulmonary/sleep landscape. To address that confusion, part of our approach is to identify clearly defined clusters of patients, identify the standards of care in the context of device selection for these patients, and provide the clinical peer-reviewed justification for that device selection. We have deliberately avoided addressing these policies in the context of payment policies because that is not our area of collective knowledge. We leave those discussions for the DME community and their advocates.

The choice of an appropriate initial and ongoing treatment plan, including the determination to use a ventilator vs a BPAP or CPAP device, is made based on the specifics of each individual beneficiary's medical condition. We believe that the clinical relationship between HMVs and

BPAP devices are so strongly interrelated that any comprehensive policy addressing HMV must also address these corollary devices. Thus, we are not recommending a particular policy structure (national coverage determination [NCD] vs local coverage determination [LCD] vs other options) for CAG to consider, especially reflective of the overlapping NCD policies currently in place that impact these intersecting patient populations. Rather, we defer to the agency to structure modifications reflecting these recommendations in a format that it determines is logical, relatively easy to implement, and yet comprehensive in nature.

In addition, as these recommendations are clinically focused, we would be remiss if we did not address a challenging component integral to the devices addressed: professional services. We see certain telehealth services as an excellent opportunity for improving access to care. We see remote monitoring as another growing opportunity. Although we understand the limitations imposed by the current statute authorizing payment for certain DME, it is important for the societies to emphasize the vitally important role that allied health professionals, particularly respiratory therapists, play in the care of these patients who are chronically ill. In fact, numerous states require direct involvement of these professionals in certain facets of HMV. CAG must not presume that any absence of reference to the integral role of respiratory therapists in the care of these patients in the home is construed in any way other than our acknowledgment of certain statutory limitations.

II. HISTORY OF MEDICARE COVERAGE

Section 280.1, Durable Medical Equipment Reference List, Pub. 100-03, National Coverage Determinations, Part 4, Chapter 1 (Effective 5, 2005):[1] Covers positive and negative pressure type ventilators for neuromuscular disease (NMD), thoracic restrictive disease (TRD), and chronic respiratory failure (CRF) consequent to COPD. The list is a quick reference tool used to determine the coverage status of certain pieces of DME and to facilitate processing of DME claims. The policy does not include patient criteria to determine appropriate device selection for the diseases stipulated in the reference list.

Local Coverage Determination L33800 (formerly L11504), Respiratory Assist Devices: Original Effective Date: October 1, 1999, Revised Effective January 1, 2020:[2] Covers BPAP without (E0470) or with a backup rate (E0471) for individuals diagnosed with severe COPD, TRD, hypoventilation syndrome (HS), and central or complex sleep apnea. Specific policies for the first 3 months of coverage for each of these diagnoses are outlined in detail later in this document. Beneficiaries covered for the first 3 months of an E0470 or an E0471 device must be reevaluated to establish the medical necessity of continued coverage but 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 reevaluation has been completed.

Numerous revisions have been made to the policies over the years. Effective December 1, 2014, CMS added a section to address ventilators with noninvasive interfaces. The policy referred to a nonbinding 2001 CMS decision memorandum that determined ventilators, in contrast to RADs, were considered reasonable and necessary only in situations when the patient's condition was severe enough that interruption of respiratory support would be "life-threatening or lead to death." The policy also stated that the disease groups covered under the NCD "may appear to overlap conditions described in the RAD LCD but they are not overlapping," noting that choice of a ventilator vs a BPAP device is made based on the severity of the condition. In December 2016, for claims effective on or after January 1, 2017, CMS changed its position. The policies addressing ventilatory support for diagnoses of NMD, TRD, and respiratory failure consequent to COPD, which remain in effect today, in part states the following:

> "Each of these disease categories are comprised of conditions that can vary from severe and life-threatening to less serious forms. These ventilator-related disease groups overlap conditions described in this Respiratory Assist Devices LCD used to determine coverage for bilevel PAP devices. Each of these disease categories are conditions where the specific presentation of the disease can vary from patient to patient. For conditions such as these, the specific treatment plan for any individual patient will vary as well. Choice of an appropriate treatment plan, including the determination to use a ventilator vs. a bilevel PAP device, is made based upon the specifics of each individual beneficiary's medical condition. In the event of a claim review, there must be sufficient detailed information in the medical record to justify the treatment selected."
>
> "A ventilator is not eligible for reimbursement for any of the conditions described in this RAD LCD even though the ventilator equipment may have the capability of operating in a bilevel PAP (E0470, E0471) mode. Claims for ventilators used to provide CPAP or bilevel CPAP therapy for conditions described in this RAD policy will be denied as not reasonable and necessary."

Section 240.4 - Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA), Pub. 100-03, National Coverage Determinations Manual, Part 4, Chapter 1 (Effective April 4, 2005) (Effective March 13, 2008) (Rev. 96, Issued: 10-15-08, Effective: 03-13-08, Implementation: 08-04-08): [3] Coverage of CPAP is considered reasonable and necessary when used in adults with OSA who meet certain criteria. Coverage is initially limited to a 12-week period if either of the following criterion are met: (1) the apnea hypopnea index (AHI) or the respiratory disturbance index (RDI) is ≥15 events/h, or (2) the AHI or RDI is at least five events and ≤14 events/h, with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders/insomnia, documented hypertension, ischemic heart disease, or history of stroke.

Local Coverage Determination L33718, Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea, Original Effective Date 1-1-2015, Revised Effective 1-1-2020. [4] Covers both a single-level CPAP device (E0601) and a bilevel RAD without back-up rate (E0470) when it is used in the treatment of OSA. An E0601 device is covered if: (A) the beneficiary has

an in-person clinical evaluation by a treating practitioner prior to the sleep test to assess the beneficiary for OSA, (B) the beneficiary has a sleep test that meets certain criteria, and (C) the beneficiary and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment. An E0470 device is covered for the treatment of OSA if criteria A - C are met in addition to (D), which is that an E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.

Section 240.2 - Home Use of Oxygen, Pub. 100-03, National Coverage Determinations Manual, Part 4, Chapter 1, (Rev. 173, Issued: 09-04-14), Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10).[5] Covers patients with significant hypoxemia in the chronic stable state, (i.e., not during a period of acute illness or an exacerbation of their underlying disease) if: (1) the attending physician has determined that the patient has a severe lung disease or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy, (2) the patient meets certain blood gas evidence requirements, and (3) the patient has appropriately tried other treatment without complete success.

Local Coverage Determination L33797, Oxygen and Oxygen Equipment, Original Effective Date: 10-01-15, Revised 8-02-2020.[6] Covers patients who meet the criteria identified in Section 240.2 above. The qualifying blood gas study must be performed by a treating practitioner or by a qualified provider or supplier of laboratory services. If the blood gas study is performed during an inpatient hospital stay, the reported test must be the one obtained closest to, but no earlier than, 2 days prior to the hospital discharge date. Coverage is divided into two groups. Initial coverage for beneficiaries meeting Group I criteria is limited to 12 months or the treating practitioner-specified length of need, whichever is shorter.

III. BENEFIT CATEGORY

Noninvasive ventilators and other types of respiratory devices such as CPAP devices and BPAP devices are covered under Medicare's DME benefit category as outlined in §1861(n) of the Social Security Act. DME is defined as equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, is generally not useful to a person in the absence of an illness or injury and is appropriate for use in the home.[7]

IV. FOOD AND DRUG ADMINISTRATION STATUS

Ventilators are indicated by the FDA to provide continuous or intermittent ventilator support for the care of individuals who require mechanical ventilation. The devices are intended to be used in the home, hospitals, and institutions, and may be used for both invasive and noninvasive ventilation (NIV). Ventilators are classified by the FDA as Class II devices, which are moderate to high-risk devices with general controls and special controls, the latter of which are generally specific to the device. In the case of ventilators, the controls are related to

performance standards. Importantly, as best we can determine, the FDA does distinguish between mechanical ventilators intended to provide life support (removal of the device would lead to significant patient harm and eventual death) and mechanical ventilators to provide support for respiratory insufficiency or less serious forms of respiratory distress. Devices with the CBK approval are approved for life support (respiratory failure) while ventilators classified as MNT or MNS are approved to treat respiratory insufficiency.

In this NCD request, we recognize we are addressing two broad categories of ventilators, namely (1) noninvasive devices used to treat respiratory failure and (2) bilevel devices used to treat documented respiratory insufficiency. Bilevel devices without a backup rate deliver adjustable, variable levels of positive pressure via tubing and a noninvasive interface, whereas such devices with backup include a timed backup feature to deliver air pressure whenever sufficient spontaneous inspiratory efforts fail.

V. CMS EXTERNAL EVIDENCE REVIEW

External Technology Assessments

As noted above, Medicare covers noninvasive ventilators for CRF consequent to COPD, (TRD) and NMD. At the request of CMS, a formal technology assessment on "Noninvasive Positive Pressure Ventilation in the Home" (Final Technology Assessment Project ID: PULAT0717 2/4/2020) was conducted by the Agency for Healthcare Research and Quality (AHRQ).[8] The purpose of the review was to evaluate home noninvasive positive pressure ventilation (NIPPV) in adults with CRF in terms of initiation, continuation, effectiveness, adverse events, equipment parameters, and required respiratory services. Devices evaluated were HMVs, BPAP devices, and CPAP devices. According to the AHRQ, both randomized and comparative nonrandomized studies were reviewed that included enrolled adults with CRF who used NIPPV for ≥1 month at home using a HMV, BPAP device, or CPAP device.

Key Findings

This systematic review included 68 studies evaluating 53,733 patients and addressed initiation and continuation of home NIPPV, including the effectiveness, equipment settings, and related respiratory services for patients with CRF. Data sources included 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 June 26, 2018. For the convenience of CMS, we have repeated the key findings reported by AHRQ as outlined below:

- In patients with COPD, home NIPPV as delivered by a BPAP device (compared to no device) was associated with lower mortality, intubations, hospital admissions, but no change in

quality of life (low to moderate strength of evidence [SOE]). NIPPV as delivered by an HMV device (compared individually with BPAP, CPAP, or no device) was associated with fewer hospital admissions (low SOE). In patients with TRD, HMV (compared to no device) was associated with lower mortality (low SOE). In patients with NMD, home BPAP (compared to no device) was associated with lower mortality and better quality of life (low SOE). In patients with obesity hypoventilation syndrome (OHS), HMV/BPAP mix (compared to no device) was associated with lower mortality (low SOE). BPAP (compared to no device) was associated with improved sleep quality.

- Current evidence is insufficient to assess the comparative effectiveness of many NIPPV device capabilities on patient outcomes, particularly comparing HMV to BPAP. Future studies should address which device capabilities are associated with improved patient outcomes.
- Criteria to initiate home NIPPV and home respiratory services were summarized in this report but varied and were not validated in comparative studies.
- Incidence of nonserious adverse events such as facial rash, dry eyes, mucosal dryness, and mask discomfort across devices was approximately 0.3 events over a median duration of device used of 6 months. The most reported serious adverse event was acute respiratory failure. Based on direct comparisons, no statistically significant differences were found in number of treatment withdrawals or adverse events when comparing different devices or when comparing device use with no device use.

Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

As noted earlier, CMS conducted a virtual meeting of its MEDCAC on July 22, 2020, to review evidence specific to the home use of NIPPV by patients with CRF consequent to COPD. Devices included HMVs, BPAP devices, and CPAP devices.

The purpose of the meeting was to seek MEDCAC's recommendations regarding the characteristics that define patient selection and use criteria, concomitant services, and equipment parameters necessary to best achieve positive patient health outcomes in beneficiaries with CRF consequent to COPD. The panel was asked to focus on the scientific evidence associated with the outcomes most pertinent to the affected patient population, e.g., decreased mortality, decreased frequency of exacerbations requiring ED or hospital admission, increased time to hospital readmission for respiratory related disease, improved function/quality of life). The scale in identifying level of confidence is the following:

1	—	*2*	—	*3*	—	*4*	—	*5*
Low Confidence				*Intermediate*				*High Confidence*

The final scoresheet provided after the meeting and reported by CMS on September 8, 2020, is repeated below.[9]

I. ***SCORE: 3.15:*** 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 admissions, hospital discharge timing, pulmonary function tests, etc.) when used with any category of NIPPV device?

II. ***SCORE: 2.85:*** 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 improve physician function and quality of life)?

III. ***SCORE: 2.23:*** 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?

IV. ***SCORE 2.38:*** 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?

VI. NCD REQUEST BY CATEGORIES OF DISEASE/SUPPORTING EVIDENTIARY DOCUMENTATION

This NCD reconsideration request is divided into major five sections: *Chronic Obstructive Pulmonary Disease*, *Thoracic Restrictive Diseases, Hypoventilation Syndrome, Central Sleep Apnea,* and *Obstructive Sleep Apnea*. To put each section's discussion in context and for the convenience of CMS staff as they review this NCD reconsideration request, we have copied the current coverage policies for the first 3 months of initial coverage for severe COPD, TRD, HS, and CSA contained in LCD (L33800), effective January 1, 2020.[2] With respect to OSA, we have copied the current coverage policies found in LCD L33718, effective January 1, 2020.[4] Although the specifics of each Medicare beneficiary's medical condition drives the decision on when to use a ventilator vs a BPAP device in developing an appropriate treatment plan, CMS has made it clear that, regardless of whether a ventilator has the capability of operating in a bilevel mode for the treatment of NMD, TRD, or respiratory failure consequent to COPD, they are not eligible for coverage if they are used to provide CPAP or BPAP therapy.

Introduction

An estimated 24 million people are living with COPD in the United Sates. COPD is the third or fourth leading cause of death,[10,11] and the annual cost of caring for patients with COPD in the United States is calculated at $49 billion (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 ventilation/perfusion mismatch and increased dead space that impair the body's ability to maintain normal oxygenation and alveolar ventilation.[12] Once hypoxemia during wakefulness reaches critical levels (Pa_{O_2} <55 mm Hg), supplemental oxygen improves survival.[13] Impairment of alveolar ventilation predisposes to progressive hypercapnia as compensatory mechanisms fail, initially during sleep, but eventually becoming diurnal.[14] In these cases, an increase in Pa_{CO_2} level above the normal threshold of 45 mm Hg is independently associated with increased mortality.[15] Studies have shown that use of NIPPV support via a mask to lower Pa_{CO_2} in such patients lowers mortality and reduces hospitalizations.[16,17] This review summarizes the framework of CMS coverage policies for use of NIV for COPD and identifies the challenges with the policies that create barriers to NIV use and result in its inappropriate applications. We also provide recommendations for solutions to these problems.

Current Coverage Criteria[2]

An E0470 device is covered if criteria A - C are met.

A. *An arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, is greater than or equal to 52 mm Hg.*
B. *Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO2 (whichever is higher).*
C. *Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out. (Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the beneficiary does not suffer from some form of sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or CompSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).*

If all of the above criteria for beneficiaries with COPD are met, an E0470 device will be covered for the first three months of therapy.
If all of the above criteria are not met, E0470 and related accessories will be denied as not reasonable and necessary.

An E0471 device will be covered for a beneficiary with COPD in either of the two situations below, depending on the testing performed to demonstrate the need.

Situation 1. For Group II beneficiaries (COPD) who qualified for an E0470 device, an E0471 started any time after a period of initial use of an E0470 device is covered if both criteria A and B are met.

A. *An arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, shows that the beneficiary's PaCO2 worsens greater than or equal to 7 mm HG compared to the original result from criterion A, (above).*
B. *A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 device that is not caused by obstructive upper airway events – i.e., AHI less than 5. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea).*

Situation 2. For Group II beneficiaries (COPD) who qualified for an E0470 device, an E0471 device will be covered if, at a time no sooner than 61 days after initial issue of the E0470 device, both of the following criteria A and B are met:

A. *An arterial blood gas PaCO2 is done while awake and breathing the beneficiary's prescribed FIO2, still remains greater than or equal to 52 mm Hg.*
B. *Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO2 [whichever is higher].*

If E0471 is billed but the criteria described in either situations 1 or 2 are not met, it will be denied as not reasonable and necessary.

Problems With Current Coverage Criteria

For patients with severe COPD, the coverage criteria noted above need to be revised. These criteria qualify a patient for a BPAP device without a backup rate (i.e., BPAP device in the "S" or spontaneous mode that requires the patient to initiate all breaths spontaneously), referred to in current local CMS policy as a respiratory assist device (RAD). The RAD terminology does not exist in the clinical literature and should be eliminated. A BPAP with a backup rate (i.e., spontaneous/timed [S/T mode]) would be covered if, after 2 months, the patient was using the device for >4/24 h, symptoms persisted, $PaCO_2$ remained ≥52 mm Hg, and overnight oxygen saturation was ≤88% for more than 5 min on the usual FiO_2.

Patients Not Receiving Appropriate Devices

In August 2003, CMS revised its policies to ensure that all BPAPs, even when used as a ventilator with a backup rate, were nevertheless paid as a capped rental item (i.e., payments stop after 13 months, and the device becomes the property of the patient). This decision attempted to distinguish reimbursement policy for BPAPs vs HMVs, the latter of which are defined as devices that need frequent and substantial servicing (FSS) and for which discontinuation or interruption would lead to the death of the patient.

Some 17 years later, technologic advances have led to overlapping of the two categories of devices (BPAPs and HMVs) used to treat patients with chronic hypercapnic respiratory failure. HMVs have 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 (VAPS), this distinction is now blurred. It is now more difficult to link 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. Furthermore, the current qualifying criteria for using a BPAP device create greater barriers to approval than with an HMV (see below). This, 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 utilization of HMVs and a huge rise in expenditures in the COPD population over the past 5 years.

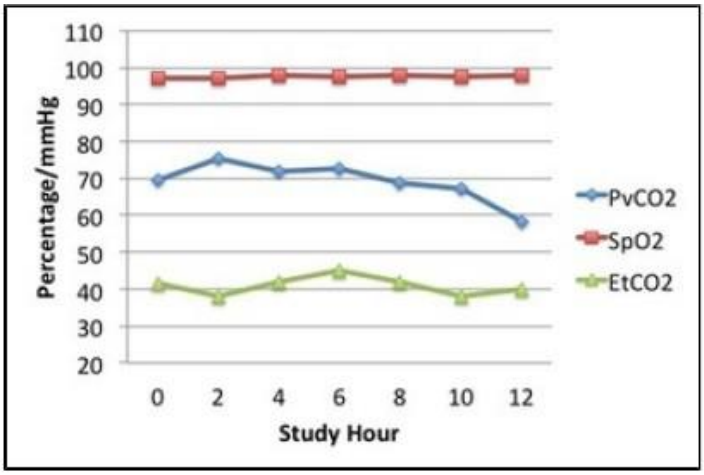
As outlined below, the problems with the current NCD for NIV in COPD can best be described in terms of case vignettes illustrating the barriers the current criteria can pose as clinicians struggle to prescribe the appropriate device.

1. **Overnight oxygen saturation ≤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:*** *JM is a 65-year-old woman with severe COPD and chronic hypercapnic respiratory failure requiring 2 L/min continuous oxygen therapy. During her usual chronic stable state, her arterial blood gas (ABG) level is checked and the PCO_2 is 52 mm Hg. Nocturnal oxygen assessment is ordered while she uses her usual 2 L/min of oxygen via nasal prongs and shows no oxygen saturation value <88% for 5 min. She is told she does not qualify for NIV and wonders if any other appropriate therapies exist 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 COPD patients with resting $PaCO_2$ > 52 mm Hg (mean $PaCO_2$, 61.5 mm Hg) had persistent hypercapnia with a median partial pressure of CO_2 in venous blood ($PvCO_2$) of 69.5 mm Hg and end-tidal CO_2 of 41.5 mm Hg despite normal SpO_2 (Figure 1).[18]

Figure 1: Severe nocturnal hypercapnia despite normoxia in hospitalized COPD patients



None of the patients had desaturations <90% despite their persistent hypercapnia. Furthermore, no studies on use of NIV for severe stable COPD or after a severe exacerbation have used this criterion for inclusion, and any evidence is completely lacking to support it. To deny NIV, which could provide the benefits the patient is seeking, based on a lack of oxygen desaturations is wrong 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 to the patient.

RECOMMENDATION: The oximetry requirement should be eliminated.

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 recently increased cough or phlegm and no recent hospitalizations. Her* 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 mml/L. The patient is started on BPAP NIV with inspiratory pressure 18 cm* H_20*. She reports inspiratory discomfort and air leakage, averages 4.5 h of nightly use, and there was no capability in the device to better optimize the flow delivery. One month later and she is not feeling better and is very fatigued in the morning. Repeat ABG shows a* $PaCO_2$ *of 62 mm Hg and serum bicarbonate of 37 mml/L. She is switched to an HMV in VAPS 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/min. On these settings, she sleeps better at night and has more energy during the day. ABG shows* $PaCO_2$ *50 cm* H_2O *and bicarbonate 32 mm* HCO_3*.*

RECOMMENDATION: HMVs should be considered in patients with **any** of the following:

- Higher inspiratory pressures than those deliverable by E0471
- FiO_2 >40% or 5 L/min nasally
- Ventilator support for ≥10 h/day (i.e., ***daytime use***)
- **Both** sophisticated alarms and accompanying internal battery (high-dependency patient)

- Mouthpiece ventilation ***during the day***
- Persistence of hypercapnia with $PaCO_2$ ≥52 mm Hg despite adequate adherence to BPAP therapy

Like patients with TRD, these patients can most easily be identified by their high ventilatory needs requiring extended ventilation times into the *daytime hours*, but the COPD patient struggles from more 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 the 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 CRF to a chronic care facility. This 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.[19] This is more fully addressed in a commentary below.

Current Evidence/Clinical Consensus Practice Guidelines

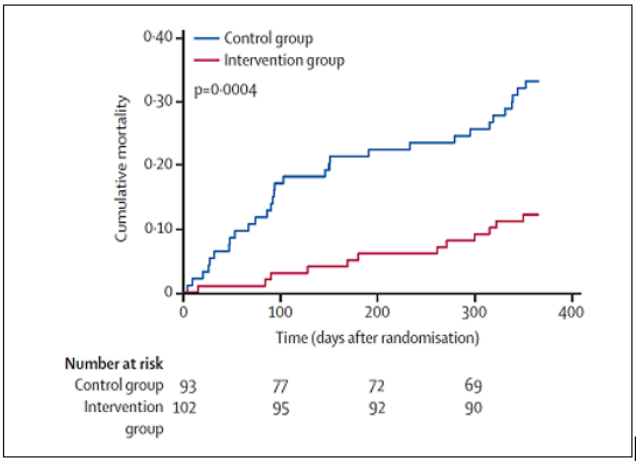
Since the current coverage guidelines were enacted, new important evidence has accrued and technology has evolved. It is time to critically reexamine the guidelines and suggest alterations that will facilitate the delivery of the right device to the right patient at the right time.

Past studies on the nocturnal home use of BPAP ventilation to treat CRF in COPD provided variable and often conflicting results.[20] In 2014, Kohnlein et al[16] published a landmark prospective, multicenter, randomized controlled trial of BPAP ventilation in patients with chronic stable hypercapnic COPD compared to optimized standard therapy. Patients had stage IV COPD, mean age **64.4 years** with resting $PaCO_2$ of 51.9 mm Hg or higher and pH >7.35.

BPAP ventilation was targeted to reduce baseline $PaCO_2$ by ≥20% or to achieve values <48 mm Hg using high inspiratory pressures **and a backup rate**. The difference in 1-year all-cause mortality rate was profound with 12% in the BPAP group and 33% in the control group (Figure 2).

Secondary improvements were also seen in FEV_1, $PaCO_2$, and pH in the BPAP group compared to the control group. 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 thought to be related to 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 physiologic suppression of respiratory drive during sleep that, combined with diaphragm dysfunction related to hyperinflation, can lead to hypoventilation and failure to trigger, especially during rapid eye movement sleep.

Figure 2. Effect of NPPV with backup rate on survival in stable severe hypercapnic COPD



Another approach to initiating BPAP in severe COPD is to intervene after admission for acute respiratory failure. This has garnered additional interest because of concerns about hospital readmission rates in COPD patients. Murphy et al[17] used this approach, enrolling 116 patients with mean age of 66.7 years and with persisting hypercapnia (>53 mm Hg) at least 2 weeks after resolution of decompensated acidosis and within 4 weeks of attaining clinical stability after hospitalization that required use of acute NIV. Patients were randomized to high-pressure NIV (average inspiratory pressure 24 cm H_2O, expiratory pressure 4 cm H_2O with a backup rate of 14/min) with home oxygen therapy (HOT) or HOT alone. The primary outcome, hospital admission or death, was again significantly different, with patients using HOT requiring readmission after a median of 1.4 months post-discharge compared to 4.3 months for patients using BPAP ventilation. One-year mortality was not significantly different between the groups, but transcutaneous PCO_2 and frequency of exacerbations were reduced, and quality of life improved in the BPAP group. Another similarly designed study by Struik et al[21] found no significant differences in readmission or mortality rates, but these patients did not manifest persistent hypercapnia.

These data provide important information regarding: (1) the level of resting hypercapnia in patients likely to benefit, (2) lack of need to perform a sleep study or nocturnal oximetry to select COPD patients with BMI <35 kg/m^2 for successful NIV, (3) the importance of using higher inspiratory pressure settings/pressure support levels than older studies and addition of backup respiratory breaths to achieve a reduction in $PaCO_2$. Although surrogate $PaCO_2$ measurements such as end-tidal or transcutaneous may be appropriate for patients with TRD or another HS, an ABG with a $PaCO_2$ is necessary for COPD patients to identify the hypoventilatory threshold

($PaCO_2$ ≥52 mm Hg) expected to benefit from NIV based on the above literature and expert opinion. Whether surrogate measurements of $PaCO_2$ can be used for qualifying COPD patients for home NIV or for monitoring subsequent responses remains to be established.

The findings from the clinical studies described above have been substantiated by Frazier et al,[22] using the Medicare Limited Data Set (2012-2018), who compared 511 COPD patients started on NIV within 2 months of receiving a diagnosis of chronic respiratory failure with 511 COPD patients matched for demographic and clinical characteristics but who were not started on NIV. One year after diagnosis, the mortality rate in the NIV group was 28% vs 46% in controls. The relative risk reduction attributable to NIV was 39% for mortality, 17% for hospitalizations, and 22% for ED visits. These results, obtained from a large US database, are consistent with the clinical trial data presented above.

As noted earlier, in 2019, the Agency for Healthcare Research and Quality contracted for a technology assessment of NIV in the home and, based on a systematic review of the literature concluded that for COPD, BPAP reduced dyspnea and mortality and increased activity of daily living, while both BPAP and HMV reduced hospitalizations.[23]

The European Respiratory Society (ERS) Task Force in 2019[24] and an American Thoracic Society (ATS) subcommittee in 2020[25] both suggested using long-term home NIV for stable hypercapnic COPD as well as for patients after hospitalization for an exacerbation requiring NIV. The ATS guideline suggested waiting for ≥2 to 4 weeks to ensure persistence of hypercapnia (conditional recommendation, low certainty), whereas the ERS 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 as is the belief of this TEP. Both guidelines also recommended ventilator settings to reduce $PaCO_2$, with the ATS guideline suggesting to "target normalization."[25] The ERS guideline also suggested "fixed pressure support" as the preferable mode.[24]

RECOMMENDATION: For patients with COPD to qualify for BPAP, we recommend removing the requirements that (1) a nocturnal oximetry study be performed using either 2 L/min nasal oxygen or the patient's usual FiO_2, whichever is higher, and 2) patients start with a BPAP device without a backup rate, and replacing these criteria with all of the following:

- Higher inspiratory pressures than those deliverable by E0471
- FiO_2 >40% or 5 L/min nasally
- Ventilator support for ≥10 h/day (i.e., ***daytime use***)
- **Both** sophisticated alarms and accompanying internal battery (high-dependency patient)
- Mouthpiece ventilation ***during the day***
- Persistence of hypercapnia with $PaCO_2$ ≥52 mm Hg despite adequate adherence to BPAP therapy

Ongoing Requirements: Once therapy is initiated, it is necessary for an established plan of care that is reflective of the patient's specific clinical needs. This plan of care should include not only documentation of initiation of the therapy but also address adherence, monitoring as appropriate, and ongoing clinical support.

Initiation

Initiation of long-term NIV may take place in the hospital setting, usually after 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 US) has not firmly established, but pressure to dismiss patients quickly from the hospital favors allowance of in-hospital initiation in the United States. Recently, a randomized controlled trial from the Netherlands showed noninferiority of home compared to in-hospital initiation of NIV for severe stable COPD.[26] 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 S/T modes, VAPS, auto-titrating expiratory positive airway pressure (auto-EPAP) 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 effectiveness of NIV (i.e., 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.[27]

Adherence

Some studies have reported lower adherence to NIV in patients with COPD compared to those with NMD, and others show similar rates of adherence, with 30% using the device <4 h/day and 13% abandoning the therapy altogether within 28 months.[28,29] The importance of adherence is highlighted by a study of 1746 patients on NIV for hypercapnic respiratory failure who were followed >6 years, of whom 20% had obstructive lung disease. [30] The single most important factor associated with a poor outcome was low adherence (NIV use <4 h/day). 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.

The experience of 479 patients receiving long-term home NIV in the Lake Geneva area of Switzerland (median age 71 years, with 31% being >75 years of age) were studied for a median of 39 months.[31] COPD constituted the largest individual group (28%); overall, 82% were initiated on NIV in the hospital and the rest in the outpatient setting. Comorbidities were very common in the COPD patients; 68% had hypertension, 46% had obesity, and 21% had probable pulmonary hypertension. In that cohort, adherence was excellent; only 8% of patients used NIV <3 h/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.

RECOMMENDATION: Based on these findings, we recommend a second 90-day trial period be included 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 COPD patients using NIV in the home include all of the following elements:

1. Targeted clinical assessment by experienced personnel familiar with the diagnosis and consequences of COPD and use of NIV
2. ABG $PaCO_2$ to determine response to therapy and help adjust the ventilator to the evolving needs of the patient
3. Nocturnal pulse oximetry as a dynamic complement (for monitoring only, not initiation) to ABG
4. Trend report from ventilator software that is now available in most modern devices; these provide information on patterns of use, synchrony and triggered breaths, respiratory rate, tidal volume, and minute volume and leaks

Need for Clinical Support of COPD Patients Using NIV

We fully recognize that the Medicare DME 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 the 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 mortality. This is especially important because the DME Quality Standards require a respiratory therapist to be available 24/7 with respect to the use of respiratory equipment. Moreover, as noted earlier, numerous states require respiratory therapists to perform clinical assessments in addition to placing any patient on the device when engaged in the initial setup and education of the patient and/or caregiver regarding the equipment.

Revised Policies for COPD

Initial NIV Setup

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 ensure adequate pressure and flow delivery throughout the breath. COPD patients 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. Indeed, some authorities recommend in-patient admissions to accomplish these goals.[32] Initial NIV setup simply cannot be accomplished in short outpatient clinic visits and certainly not by recorded/printed material alone. We advocate for the provision of frequent visits to the patient's home by skilled respiratory therapists who can then make the necessary adjustments to optimize the likelihood of success.

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. 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 phone or telemedicine, these tasks are more reliably performed via face-to-face home visits where both the ventilator and patient can be directly observed. Dedicated respiratory therapists who are experts in NIV operations are needed on 24-h hot lines as well as being readily accessible for in-home visits.

Ongoing Support

A strong evidence base supports the necessity of ongoing clinical/technical support for these patients. The 2020 AHRQ evidence-based review identified 36 studies showing benefit of NIV in hypercapnic COPD patients. These studies were extended up to 48 months, and all of them had ongoing clinical/technical support in some form for the duration of the trial.[23] This is also a common clinical practice and the standard of care in most European NIV programs.

Conclusion

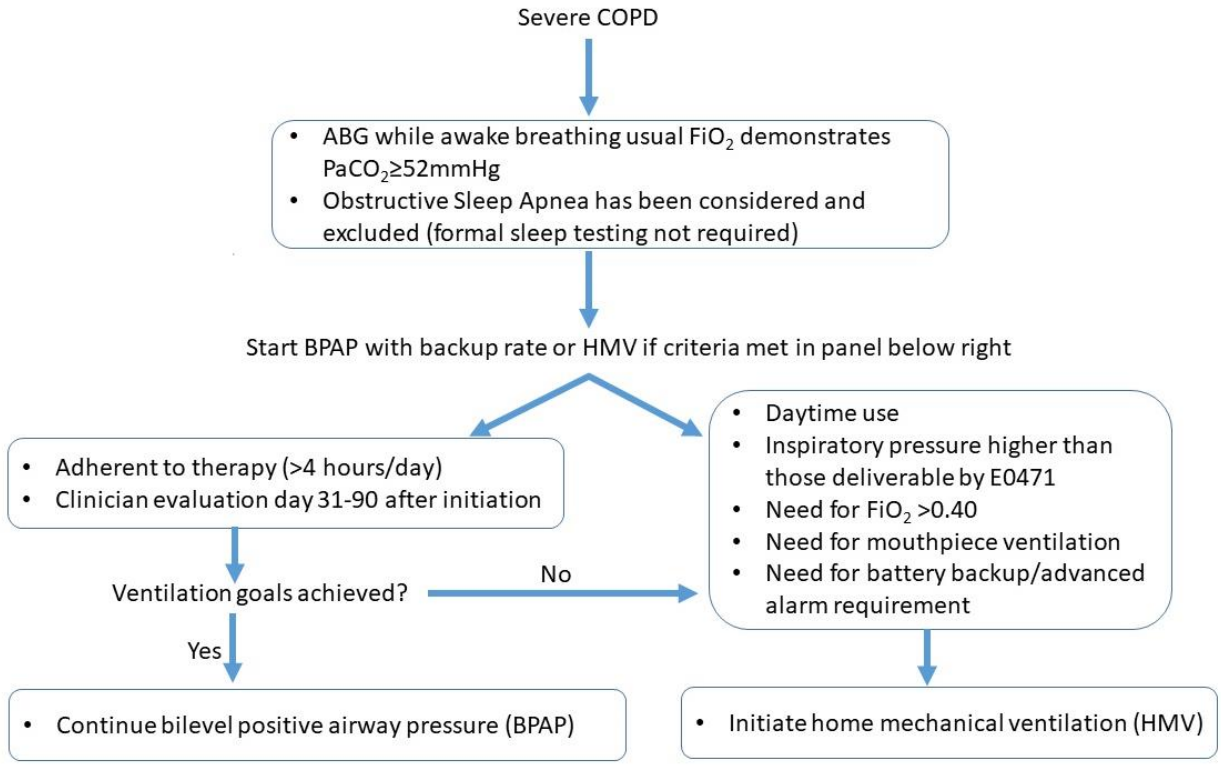
The COPD TEP concluded that the expertise of experienced clinicians (e.g., respiratory therapists) to provide the needed support for individuals on home NIV is critical to patient care and avoidance of risk to the patient, and this is true whether patients are using a RAD or HMV. We would strongly urge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

services provided by respiratory therapists in the home are not reimbursed, making it difficult to provide these services, especially for patients on NIV via BPAP.

Summary of New Recommendations

Figure 3 below summarizes our recommended 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 need 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.

Figure 3. Flow diagram of recommended requirements for coverage of BPAP and HMV in patients with COPD and chronic hypercapnic respiratory failure.



THORACIC RESTRICTIVE DISEASE

Introduction

TRD is characterized by restrictive respiratory physiology due to weakness from NMD, chest wall deformity, or both. TRD often leads to disturbed sleep architecture, sleep hypoventilation, and, ultimately, daytime hypoventilation.[33,34] The leading causes of death and major morbidity in these diseases are respiratory infection and respiratory failure.[35] Classes of disease leading to

TRD-related CRF can include defects in generation of respiratory drive (e.g., congenital central hypoventilation syndrome), upper airway weakness or instability (e.g., amyotrophic lateral sclerosis [ALS]), weakness of the diaphragm and other respiratory muscles (e.g., muscular dystrophies, ALS, diaphragmatic paralysis), or thoracic cage deformities (e.g., severe scoliosis).

Initially, NIV was employed to treat TRD, beginning during the polio epidemics of the mid-twentieth century in the form of negative pressure ventilation with the "iron lung" and, from that time, reduction in mortality and improvement of quality of life have been universally demonstrated.[36] Patients with TRD require NIV support for anywhere between a few hours to a substantial portion of the day, using a mask at night and a mouthpiece during the day. Today, daytime mouthpiece ventilation can only be realistically supplied by an HMV (not BPAP devices), illustrating why many patients with TRD will use HMVs (not BPAP devices) via noninvasive interfaces.

The current policies covering noninvasive respiratory support for individuals with TRD were originally based on recommendations of a consensus conference of experts organized in 1998 by the American College of Chest Physicians (CHEST) and the National Association for Medical Direction of Respiratory Care (NAMDRC).[1,37]

Current Coverage Criteria[2]

An E0470 or E0471 device is covered when criteria A – C are met.

- *A. There is documentation in the beneficiary's medical record of a neuromuscular disease (for example, amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB).*
- *B. One of the following:*
  - *a. An arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2 is greater than or equal to 45 mm Hg, or*
  - *b. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the beneficiary's prescribed recommended FIO2, or*
  - *c. For a neuromuscular disease (only), either i or ii,*
    - *i. Maximal inspiratory pressure is less than 60 cm H20, or*
    - *ii. Forced vital capacity is less than 50% predicted*
- *C. Chronic obstructive pulmonary disease does not contribute significantly to the beneficiary's pulmonary limitation.*

If all of the above criteria are met, either an E0470 or an E0471 device (based upon the judgment of the treating practitioner) will be covered for the first three months of therapy.
If all of the above criteria are not met, then E0470 or E0471 and related accessories will be denied as not reasonable and necessary.

Problems With Current Coverage Criteria

Although NIV improves both quality and length of life, substantial barriers exist to the optimal clinical care of patients with TRD. These barriers are discussed in the following section.

Barrier 1: Delays in Implementing NIV Treatment

Three major factors cause delay in implementation of NIV:

1. Failure to acknowledge symptoms as a major component of coverage
2. Difficult to measure and excessively stringent functional criteria (e.g., spirometry, muscle pressure measurements, oxygen/CO_2 assessment). Currently, measurement of vital capacity (VC) and maximal inspiratory pressure (MIP), and a measure of arterial blood CO_2 level are measures mandated by CMS policies
3. Lakc of patient access to laboratorie to undergo functional measurements

Patients with TRD have limited access to care for hypoventilation because of the numerous hurdles that our standard health-care models present. For example, travel to a clinic may be challenging for patients due to the need for specialized transport. Once at the facility, obtaining spirometry testing is another challenge, because many pulmonary function laboratories use plethysmographic ("body-box")-based systems that cannot accommodate a wheelchair and will not allow for supine measurements. A potential solution for this lack of access is home-based spirometry testing.[38,39]

Barrier 2: Lack of Coverage for Many Nonprogressive NMDs

Although over the years some nonprogressive TRDs have received positive coverage decisions, several nonprogressive NMDs result in hypercapnic respiratory failure (e.g., phrenic nerve/diaphragm disorders, spinal cord injury, quadriplegia). They may also require additional diagnostic testing, thereby delaying needed therapy in symptomatic patients who are above the qualifying thresholds or in those who cannot perform the required testing because of features of the disease (e.g., bulbar symptoms in cerebral palsy).

Barrier 3: Lack of Clear Policy Indications for HMV Support in TRD

The system in place for providing home-based ventilation support to those with NMD should in most cases start with use of a BPAP device with a backup rate. However, an HMV may be initially indicated for some individuals with TRD due primarily to diaphragm failure, especially if their disease is rapidly progressing or they present with late-stage disease. Presently, no clear, specific clinical indicators satisfy CMS coverage criteria for HMV. Some practitioners prescribe an HMV as the initial device over bilevel devices for the reasons shown in Table 1.

Table 1. Reasons cited for selection of HMV over bilevel devices	
1.	Respiratory therapist support in the home is not available with BPAP devices.
2.	Physicians and homecare companies feel the current CMS guidelines for use of bilevel devices are so obstructive that an HMV is easier to approve.
3.	Current bilevel guidelines are out of date with the medical standards, especially for ALS.
4.	Historically, volume-cycled modes of ventilation were used exclusively to treat patients when the data encourages an early start for NIV with NMD.
5.	Desire to use HMV early in the course of disease to facilitate lung volume recruitment.
6.	Health-care providers in rural areas or hurricane zones feel that assured battery backup is always needed.

The Frequent and Substantial Servicing (FSS) plan provides continuous rental payments for the HMV, and it is the only mechanism to fund home-based services provided by respiratory therapists. In addition, it is now well established that symptomatic patients with NMD need NIV, but the BPAP criterion is so outdated and so challenging to fulfill that physicians may simply give up and prescribe an HMV. The extra cost is outweighed by avoiding the burden of the BPAP criterion.

These reasons appear completely appropriate; however, it is likely that there is both a purely optional use of HMV in early progressive TRD and a subsequent necessity in more advanced disease in which NIV ***daytime*** support with a portable HMV is indicated.

Current Evidence/Clinical Consensus Practice Guidelines

Over the last 20 years (particularly for the treatment of ALS), earlier treatment with NIV has been shown to improve outcomes. In a randomized controlled trial, Bourke et al[40] showed that survial and quality of life were improved in the NIV treatment group. Patients were started on NIV based on the symptoms of orthopnea with an average FVC of 56%. This study was followed by a retrospective study of patients with ALS who were started on “early NIV” (FVC >65%) and a standard group (FVC <65%).[41] In addition to reduced FVC, patients were enrolled based on symptoms, specifically dyspnea, orthopnea, and fragmented sleep. Those in the early NIV group were found to have up to 1 year of prolonged life vs the standard group. A more recent retrospective cohort analysis also supports the use of “early NIV” in ALS prior to deterioration in VC. At an FVC <80% with symptoms, the addition of NIV was associated with an additional 7 months of survival.[42] This increases to ≈11 months with improved adherence to NIV.

Based on the above data and consensus expert opinion, many international professional society guidelines have strongly advised earlier intervention with NIV support (Table 2).[4,11-14,16-18,36,43-50] The more up-to-date international statements substantially expand criteria for NIV as compared to the current CMS coverage policies. US policies have remained in line with the CMS criterion because of the funding limitations of the current system. A very important and

consistent message from these international guidelines is that patient symptoms play a crucial role in determining application of NIV in individuals with TRD.

Table 2. International Guidelines and Criteria for Initiation of Assisted Ventilation

		Criteria for Assisted Ventilation (any of the following)				
Source	**Diagnosis**	**Symp Signs**	**Spirometry**	**Respiratory muscle pressure**	**Awake/daytime Hypoventilation/ Oxygenation**	**Nocturnal sleep Hypovent/Oxygenation**
AAN [16]	MND	Orthopnea	FVC < 50%	– MIP < - 60 cmH_2O – SNIP < -40 cmH_2O		Nocturnal oximetry < 90% for 1 cumulative minute
AFM [13]	NMD		VC < 50%		$PaCO_2$ > 45 mmHg	– Nocturnal hypercapnia
		Symptoms indicative of hypoventilation (morning headaches, fatigue, etc.) and nocturnal hypoxemia: O_2 sat < 88% for ≥ 5 consecutive mn or < 90% for > 5% of nocturnal time				
AHRQ [4]	NMD/RTD		– FVC < 40% in RTD – FVC < 50% in NMD	MIP < -60 cmH_2O	$PaCO_2$ > 45 mmHg	O_2 sat < 88% for ≥ 5 consecutive mn
ASA / TSANZ [11]	NMD		VC < 50%	MIP < 40%	$PaCO_2$ ≥ 45 mmHg	– SaO_2 < 90% for > 2 consecutive mn
						– SpO_2 ≤ 88% or less for ≥ 2% of sleep time or ≥ 5 continuous min – AHI ≥ 5.
German Society for Pneumology [17]	NMD/RTD	– Symptoms and rapid significant VC decline – Symptoms and $PaCO_2$ ≥ 45 mmHg				
		Symptoms and either of nocturnal PaCO2 ≥ 50 mmHg or $TcCO_2$ rise ≥ 10 mmHg (obtain PSG with TcCO2 when VC < 70%)				
NICE [12]	MND		VC < 50%	-SNIP/MIP < - 40 cmH_2O -Decrease in SNIP/MIP > 10 cmH_2O per 3 months		
		Symptoms or signs (especially orthopnea) with VC< 80% or SNIP/MIP < -65 cmH_2O men and < 55 cmH_2O women				

						– SaO_2 < 90% for > 5% of night – Et/$TcCO_2$ >50mmHg for >50% of sleep – Et/$TcCO_2$ rise >8mmHg above wake
		Symptoms of significant nocturnal obstructive or hypopneic events (obtain PSG for history of sleep disordered breathing or FVC < 40%, base excess > +4mmols/L on ABG or erect/supine fall in VC ≥ 25%)				
CTS [18]	MND	Orthopnea	FVC < 50%	– SNIP < - 40 cmH_2O – MIP < - 40 cmH_2O	Arterial or capillary pCO_2 > 45 mmHg	
		Symptoms AND FVC sitting or supine < 80% AND SNIP < -50cmH_2O or MIP < -65 males or < -55 females				
		Symptoms and nocturnal O_2 sat < 90% for > 5% of sleep time or < 88% for ≥ 5 consecutive mns, or ≥ 10mmHg increase in $TcCO_2$ during sleep				
DMD Care Considerations Working Group [14]	DMD	Symp Signs	FVC < 50%	MIP < - 60 cmH_2O	– CO_2 ($EtCO_2$, $TcCO_2$, arterial venous or capillary) > 45 mmHg – Awake baseline SpO_2 < 95%	– $EtCO_2$/$TcCO_2$ > 50 mm Hg for ≥ 2% of sleep time – Increased Et/$TcCO_2$ of 10 mm Hg above awake baseline for ≥ 2% of sleep time,

- Signs and symptoms: Dyspnea, tachypnea, orthopnea, disturbed sleep due to nocturnal desaturation/arousals including frequent nocturnal awakenings or difficult arousal, awakenings with dyspnea and tachycardia, or frequent nightmares daytime fatigue, difficulty concentrating, daytime hypersomnolence, use of auxiliary respiratory muscles at rest, paradoxical respiration.
- Associations: **AAN:** American Academy of Neurology; **AFM:** Association Française contre les Myopathies; **AHRQ:** Agency for Healthcare Research and Quality (US); **ASA/TSANZ:** Australasian Sleep Association/Thoracic Society of Australia and New Zealand; **CTS:** Canadian Thoracic Society; **EFNS:** European Federation of Neurological Societies; **NICE:** National Institute for Health Care and Excellence (UK).
- Disease abbreviations: **DMD:** Duchenne Muscular Dystrophy; **MND:** Motor Neuron disease; **NMD:** Neuromuscular disease; **RTD:** Restrictive Thoracic disorders.
- Testing abbreviations: **$EtCo_2$/$PaCO_2$/$TcCO_2$:** End tidal/arterial/transcutaneous CO_2; **FVC/VC:** (Forced) vital capacity; **MIP:** Maximal inspiratory pressure; **PSG:** Polysomnogram; **SNIP:** Sniff nasal inspiratory pressure. Note SNIP is negative and "<" is read as 'worse than'.

Functional Measures of Neuromuscular Weakness

There has been significant advancement in the understanding of the best measures of respiratory function in the individual with TRD.

Spirometry

VC is a significant predictor of survival, sleep-disordered breathing, nocturnal hypoventilation, and daytime hypercapnia.[51] Studies confirm the importance of VC as a predictor of survival in ALS and Duchenne muscular dystrophy (DMD).[52,53] The CMS coverage criteria of FVC <50%

predicted as the minimal finding for initiation of NIV is clearly too restrictive. The policy fails to consider those who are symptomatic with a lesser reduction in their FVC. Although FVC is the most commonly used measurement, slow vital capacity (SVC) may be easier to perform and equivalent to the FVC.[54,55]

Measures of Respiratory Muscle Strength

MIP, also known as Pimax, predicts survival, has been used as an end point of clinical trials, and is a sensitive predictor of nocturnal hypoxemia.[56,57] The sniff nasal inspiratory pressure (SNIP) is an alternative to Pimax to assess respiratory muscle weakness. Whereas Pimax assesses global inspiratory muscle strength, SNIP assesses diaphragm weakness and can be easier to perform for those with bulbar dysfunction.[58,59]

Gas Exchange Measures

Elevation in PCO_2 is universally accepted as the hallmark of hypoventilation, and ABG is the standard for measurement. Daytime hypercapnia predicts benefit from NIV and is a sensitive predictor of sleep hypoventilation.[40,60] ABG sampling is the only measure currently recognized by the CMS policies for measurement of gas exchange. The venous blood gas (VBG) PCO_2, end-tidal CO_2 ($EtCO_2$), and transcutaneous CO_2 ($TcCO_2$) are measures that have been successfully used as surrogates for $PaCO_2$. The $TcCO_2$ measurements have been shown to track closely with ABG values.[61] VBG values can track with the $PaCO_2$ on ABG but are known to exceed the value by ≈5.[62] The $EtPCO_2$ has been commonly used in patients with NMD in sleep laboratories. Although this method is known to frequently report false negatives when evaluating these patients for hypoventilation, false positives are not an issue. The ease of use and low cost suggest that $EtCO_2$ will continue to be frequently used with confidence and that elevated values reliably identify hypoventilation.[63]

Nocturnal hypoventilation without diurnal hypercapnia is a strong predictor of daytime respiratory failure within 12 to 24 months.[64] Nocturnal hypercapnia is defined by a mean $TcCO_2$ value >50 mm Hg or as an increase in $TcCO_2$ value ≥10 mm Hg to a value >50 mm Hg for ≥10 min.[65] In a randomized study, initiation of NIV in ALS for nocturnal desaturation (<90% for 1 cumulative min) improved quality of life compared to initiation at a more conventional FVC <50%.[66] Furthermore, successful correction of nocturnal desaturation with NIV in patients with ALS improved survival.[67]

Revised Policies for Thoracic Restrictive Disease

Proposed Solutions to Barrier 1: Delays in Implementing NIV Treatment

Our proposal for the revision of CMS NCD and related policies for NIV initiation is shown in Table 3, incorporating strong emphasis on patient symptoms combined with more appropriate

cutoffs for functional measurements. In addition, we propose the use of alternative physiologic measurements that may be both more accessible and easier to perform for the patient.

Table 3: Indications for Initiation of a Bilevel Device	
	Any single criterion sufficient to initiate bilevel device in TRD
1.	Symptoms plus VC < 80% • Orthopnea, dyspnea, morning headache, daytime sleepiness, or unrefreshing sleep
2.	CO_2 measurement • Daytime/Awake CO_2 ≥45 mm Hg via ABG • $EtCO_2$/$TcCO_2$ or VBG PCO_2 ≥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 SVC) • ≤50% predicted
5.	MIP/SNIP is less negative than the values below • MIP ≤ –60 cm H_2O (equal or worse than) • SNIP ≤ –40 cm H_2O (equal or worse than)

Proposed Solutions to Barrier 2: Lack of Coverage for Many Cases of Nonprogressive NMD

Revised CMS policy should allow coverage of TRDs that are nonprogressive, including (but not limited to) phrenic nerve injury, spinal cord injury, cerebral palsy, multiple sclerosis, spina bifida, and congenital central hypoventilation syndrome, as categorized in the following diagnostic groups that represent an updated TRD category:

- Spinal cord injury
- Muscular dystrophy
- Motor neuron diseases
- Ion channel diseases
- Myopathies
- Mitochondrial diseases
- Neuromuscular junction diseases
- Peripheral nerve diseases
- Impaired respiratory drive disorders
- Thoracic cage abnormalities

Proposed Solution to Barrier 3: Clear NCD Indications for HMV Support in TRD

We propose that updated CMS policies for NIV in TRD clearly incorporate indications as noted below for coverage of HMV used either in transition from BPAP to HMV or as the initial NIV device.

Any Finding Needed to Advance to HMV Following Nocturnal Use of BPAP:

- VC decreases to 30%
- NIV is needed for >**10 h/day**
- Severe breathlessness (e.g., with eating or speaking)
- Worsening **daytime** hypercapnia with need for mouthpiece ventilation
- **Daytime** dyspnea relieved by NIV

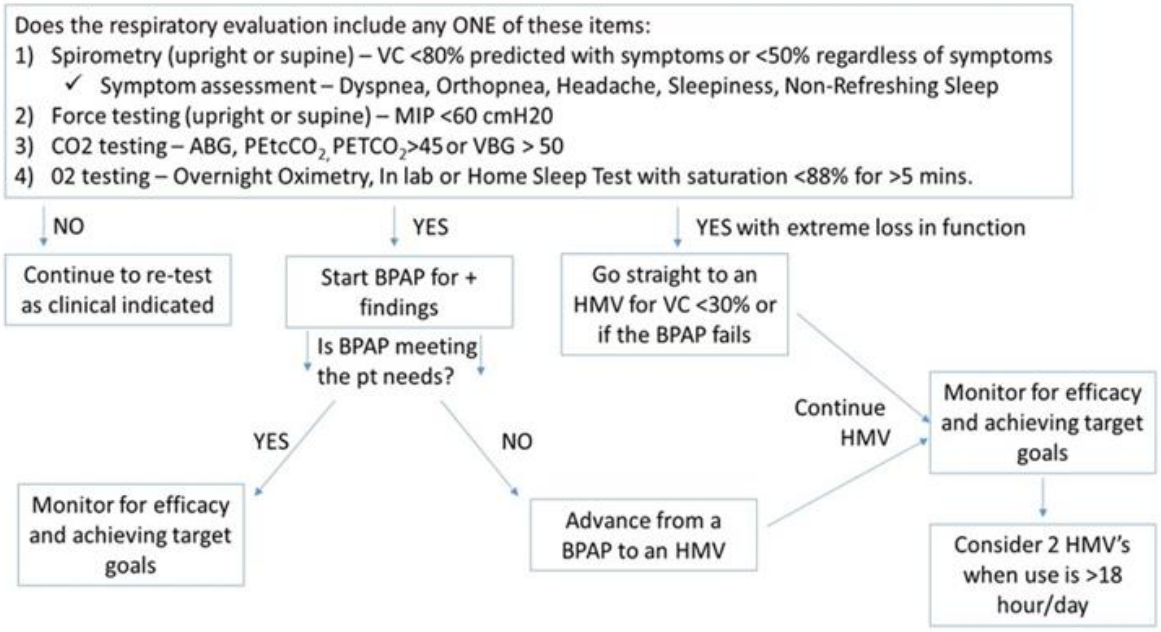
Both Findings Needed to Start With HMV as Initial NIV Device in TRD

- VC <30%
- Bilevel device transition to HMV findings (as above) present on initial presentation

Summary of New Recommendations

We propose that an updated CMS NCD policy for NIV in TRD incorporate a clear pathway for coverage of HMV as noted in the Figure 4 below.

Figure 4: Suggested initiative and monitoring of non-invasive therapy in TRD



Other Issues for Consideration

Frequent and Substantial Servicing

Patients with TRD face CRF that is both debilitating and potentially deadly. Malfunction of a bilevel device in this patient population can lead to very significant and dangerous clinical situations. While we strongly support the use of certain bilevel devices in TRD, the fact that payment is a capped rental and does not include FSS results in potentially dangerous situations for patients with TRD. We recommend the FSS provision of the statute apply to BPAP or HMV in the comparatively narrow the TRD population.

RECOMMENDATION: The frequent and substantial servicing provision of the statute should apply to BPAP or HMV in the comparatively narrow TRD population.

Criterion for Evaluation of Efficacy and Compliance for BPAP and HMV

After the initiation of BPAP, efficacy and compliance should be closely monitored. The BPAP device will be *targeted* for ≥4 h/day on ≥70% of nights, as this has been shown to impact outcomes in ALS but an all-night usage will be encouraged.[68] These patients are the most vulnerable of all the other TEP categories and should be given every opportunity to adapt to NIV, and continued coverage for patients still using the device and engaged with their NIV treating physician should be allowed coverage indefinitely once initiation criteria are met and not held to any arbitrary 4-h threshold.

Alternatively, use outside the sleep period suggests that portability and daytime mouthpiece ventilation are being used. Typically, it is assumed that the overnight sleep time does not last >9.5 h and, once use lasts >10 h, it should be assumed that at least some daytime use is needed outside of normal sleep. Utilization of NIV using an HMV should be closely monitored for compliance and efficacy. Any <u>daytime</u> use of mouthpiece or mask ventilation suggests that the HMV should continue. This could be demonstrated by finding either the total use >10 h/day or use of NIV setting >2 h during daytime.

<u>Evaluation of NIV in TRD</u>

- BPAP: No usage criteria for coverage termination
- HMV
    - One HMV:
        - >10 h/day *or*
    - Two HMVs
        - >18 h/day of NIV use
        - Need for mobility on motorized wheelchair platform

Second Device for Safety at Home

When patients progress to using an HMV for >18 h/day, this action strongly suggests that the patient is essentially ventilator dependent and should have a second device. At least one of the two devices should be portable so that wheelchair attachment and mobility are possible. These patients are at risk for hospital admission, injury, or even mortality if they have only one device and it fails. This is consistent with our current model for in-home NIV care for those with NMD who require an HMV.

HYPOVENTILATION SYNDROMES

Introduction

Hypoventilation syndromes are a heterogeneous group of disorders caused by loss of normal homeostasis and are characterized by hypercapnia, defined as a $PaCO_2$ ≥45 mm Hg at sea level. NIV is effective in improving hypercapnia and accepted as standard of care for treating various hypoventilation syndromes. Obesity is a leading cause of hypoventilation in the US, and obesity hypoventilation syndrome (OHS) refers to the development of awake daytime hypercapnia in obese individuals (BMI ≥30 kg/m^2) in the absence of other known causes of hypoventilation. OHS is associated with significant morbidity and higher risk of hospitalizations, ICU utilization, and death.[69-73] Since guidelines issued in 1998, further clinical evidence, including the largest randomized trial to date, has reinforced the benefits of positive airway pressure (PAP) in treating OHS.[74,75]

Many hypoventilatory syndromes with hypercapnic respiratory failure are included in this category such as those caused by obesity (e.g., OHS), central respiratory drive depression associated with medication or substance use (e.g., opioids), and decompensated hypercapnic respiratory failure other than COPD and NMD (increased work of breathing due to increased respiratory system load (e.g., end-stage interstitial lung disease [ILD]). Urgency is needed to reevaluate the current coverage criteria for both DME devices and respiratory support services to ensure the most appropriate care of patients with hypoventilation syndromes requiring NIV.

Current Coverage Policies[2]

An E0470 device is covered if both criteria A and B and either criterion C or D are met.

- *A. An initial arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, is greater than or equal to 45 mm Hg*
- *B. Spirometry shows an FEV1/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for beneficiaries with FEV1/FVC less than 70%.)*
- *C. An arterial blood gas PaCO2, done during sleep or immediately upon awakening, and breathing the beneficiary's prescribed FIO2, shows the beneficiary's PaCO2 worsened greater than or equal to 7 mm HG compared to the original result in criterion A (above).*

D. *A facility-based PSG or HST demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.)*

If the above criteria are not met, E0470 and related accessories will be denied as not reasonable and necessary.

An E0471 device is covered for a beneficiary with hypoventilation syndrome if both criteria A, B, and either criterion C or D are met:

A. *A covered E0470 device is being used.*
B. *Spirometry shows an FEV1/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for beneficiaries with FEV1/FVC less than 70%).*
C. *An arterial blood gas PaCO2, done while awake, and breathing the beneficiary's prescribed FIO2, shows that the beneficiary's PaCO2 worsens greater than or equal to 7 mm HG compared to the ABG result performed to qualify the beneficiary for the E0470 device (criterion A under E0470).*
D. *A facility-based PSG or HST demonstrates oxygen saturation less than or equal 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5 while using an E0470 device. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.)*

If the criteria above are not met, an E0471 device will be denied as not reasonable and necessary.

Problems With Current Coverage Criteria

The current coverage criteria for BPAP devices with a backup rate used to provide NIV have resulted in overly restrictive regulatory barriers to the delivery of appropriate equipment to support patients with hypoventilation syndromes.[76] New evidence has emerged, yet the existing criteria for reimbursement of BPAP devices with a backup rate (BPAP S/T) for hypoventilation syndromes are cumbersome, leading to delays in initiation of therapies known to improve outcomes, including mortality. [77] By failing to recognize the spectrum of disease severity and advances in technology, the current coverage criteria have led to inappropriate use of costly HMVs when BPAP S/T devices may alone suffice.

The criteria contained in CMS' current coverage policies are particularly challenging and burdensome for hospitalized patients, and they have led to both inappropriate use of HMVs and inappropriate/ineffective treatments such as supplemental oxygen alone.[2] Hospital discharge with PAP has been shown to reduce mortality at 3 months following acute respiratory failure or CRF in patients suspected of having OHS. The 2019 ATS clinical practice guidelines for management of OHS recommends such patients hospitalized with respiratory failure be discharged with NIV until they undergo outpatient diagnostic procedures.[78]

Extending DME coverage beyond 3 months currently requires that the patient be reevaluated by the treating physician at 61 to 90 days with confirmed adherence of ≥2 h/day for 21 of 30 days (70%). Initial acclimation and subsequent access to sleep physicians and sleep studies are

problematic. Many patients discharged on NIV are cared for at intermediate-care facilities, including short-term rehabilitation, prior to returning home. The existing criteria for continued DME coverage are not forgiving to these challenges, and withdrawing therapies based on an arbitrary threshold of adherence and a follow-up period, especially in these often-debilitated patients, is concerning.

Current Evidence/Clinical Consensus Practice Guidelines

Comorbidities and Mortality in OHS

In comparison to hospitalized eucapnic obese patients, those with hypoventilation have higher rates of intensive care transfers, mechanical ventilation, long-term care needs, and mortality.[79,80] The in-patient mortality among those with OHS in need of NIV for acute-on-chronic hypercapnic respiratory failure ranges from 0% to ≤15%.[69,71,73,80] Of those discharged, Meservey et al[80] showed a 30-day readmission rate of 23% in a mixed population of patients with hypercapnic respiratory failure, with 66% of the readmissions related to recurrent hypercapnic respiratory failure. In those with OHS identified on the general medicine wards, Nowbar et al[69] found an estimated mortality rate of 23% at 18 months post-discharge (hazard ratio 4.0; 95% CI, 1.5-10.4) vs those with simple obesity. In this same study, despite a high post-discharge mortality rate, BPAP therapy for hypoventilation was initiated in only 13% of the patients with OHS.[69] In another observational study of 600 hospitalized patients with OHS, of whom 61% were initially admitted to the ICU, 15% died in the hospital, and the 3-year all-cause mortality rate was 31%.[73] Unfortunately, it is unclear what percentage of patients who survived hospitalization eventually received outpatient PAP therapy. In comparison to patients with OHS discharged without PAP therapy, Mokhlesi et al[77] have reported a decreased 3 and 6-month mortality rate in these patients initiated on BPAP S/T at time of discharge (3-month mortality rate: 2.3% treated vs 16.8% untreated; $P < .0001$ and 6-month mortality rate: 4.9% treated vs 22.7% untreated; $P < .0001$). In a retrospective observational cohort study, Berg et al[81] showed that, in the 2 years after a diagnosis of OHS and the initiation of PAP treatment, a significant reduction was observed in out-patient physician costs and days of hospitalization/year (5 years prior, 7.9 days/patient-year; 2 years after, 2.5 days/patient-year [$P = .01$]). These data indicate that OHS identifies patients at a high risk of 30-day readmission and mortality due to untreated recurrent hypercapnic respiratory failure.

PAP Therapy

The BPAP mode provides more ventilatory support to effectively unload accumulated CO_2 during hypoventilation than CPAP. Adding the backup rate with the BPAP S/T provides additional mechanical breaths should the patient's breath rate fall below the preset backup respiratory rate needed to keep a minimum minute ventilation.

VAPS is a BPAP-S/T mode that auto-adjusts inspiratory positive pressure to maintain either a consistent preset target expiratory tidal volume or minute ventilation depending on the device's proprietary algorithm. Based on current technology, VAPS may also adjust the respiratory rate to treat hypoventilation and apply auto-EPAP to stabilize an open upper airway in the event of increased resistance (e.g., OSA).

Benefits of BPAP or VAPS Over Lifestyle Modifications Alone

When compared to lifestyle counseling alone, BPAP has consistently proven to be more effective on short- and long-term outcomes. Several observational studies have shown that BPAP therapy produced improvements in gas, symptoms, and measures of health-related quality of life. Furthermore, observational studies of PAP therapy have been associated with long-term improvement in mortality as well as a reduction in hospitalization days vs no therapy.[82]

In patients with OHS and concomitant severe OSA, randomized controlled trials have shown BPAP S/T and VAPS therapy significantly decrease daytime $PaCO_2$, sleep-disordered breathing, and daytime sleepiness, and they improve health-related quality of life vs lifestyle changes alone.[74] Furthermore, VAPS therapy resulted in significant improvements in pulmonary function and functional capacity (6-min walk distance test).[74]

In OHS without concomitant severe OSA, Masa et al[75] found that VAPS therapy was more effective than lifestyle modification in improving blood gas parameters, a health-related quality-of-life measure (physical component of the 36-item Short Form), and daytime sleepiness. VAPS therapy led to reduce ED visits, and post hoc analysis of adherence subgroups showed that higher level of adherence to VAPS therapy was associated with reduced ED visits and mortality.[83]

Benefits of BPAP S/T or VAPS vs CPAP

Several randomized controlled trials have shown similar treatment effectiveness among different BPAP modes (bilevel S or S/T and VAPS mode) compared to CPAP in patients with OHS and concomitant severe OSA. In the largest clinical trial, VAPS and CPAP therapy resulted in similar outcomes such as hospital resource utilization, BP, ABG parameters, spirometry, quality-of-life measures, clinical symptoms, and supplemental oxygen therapy. Both VAPS and CPAP also similarly improved pulmonary artery pressure and left ventricular diastolic dysfunction.[84]

Benefits of VAPS

There is growing evidence that VAPS is as effective as manually titrated BPAP S/T for treating respiratory insufficiency or failure. In OHS, VAPS therapy has shown to have similar treatment effectiveness in controlling sleep-disordered breathing and gas exchange when compared to

BPAP S/T.[85] Auto-EPAP technology in VAPS modes may facilitate outpatient PAP setup with a device achieving titration in the home environment and reducing the health-care utilization of polysomnography (PSG) studies. In a randomized crossover study, Orr et al[86] showed that auto-EPAP was noninferior to manual EPAP to control upper airway obstruction while remaining effective at treating hypoventilation without requiring titration by a sleep laboratory technician.

The TEP recognizes that VAPS with an auto-EPAP feature is currently available only in HMV in the US. As such, we suggest that hospitalized patients be discharged on BPAP S/T with a back-up rate and empiric EPAP setting. VAPS with auto-EPAP may be considered when the auto-EPAP feature is readily available in RADs, as it is currently in Europe. However, if failure of empiric BPAP S/T is a concern, then VAPS with auto-EPAP may be clinically indicated and its prescription via HMV should be at the provider's discretion while the patient is awaiting outpatient workup.

Transition From BPAP-ST/VAPS to CPAP in Stable Ambulatory OHS With Severe OSA

The medical literature suggests that many patients with OHS and concomitant severe OSA initially treated with BPAP S/T or VAPS can be safely switched to CPAP after a period of 2 to 3 months of nocturnal BPAP S/T therapy.[87,88] This step-down intervention applied to OHS with coexistent severe OSA has the potential to deliver effective health care at a lower cost for much of the population.

Although CPAP could become a suitable therapy for the majority of patients with OHS and concomitant severe OSA, some cases complicated by weight gain, the need for oxygen supplementation after discharge, and CPAP failure may require continuation of BPAP S/T or VAPS therapy to remain eucapnic. Therefore, the effectiveness of CPAP therapy for patients with OHS and severe OSA should be evaluated with in-laboratory titration PSG 2 to 3 months after hospital discharge while on NIV. Once switched to CPAP, patients will need follow-up care to ensure adequate response to therapy. By contrast, for those patients with OHS but without severe OSA, BPAP S/T or VAPS is recommended as the long-term therapy of choice.

In 2019, the ATS published clinical guidelines recommending that CPAP therapy rather than NIV should be considered as first-line treatment in stable ambulatory patients diagnosed with OHS and concomitant severe OSA (conditional recommendation, very low level of certainty in the evidence).[10] The ATS panel concluded that NIV may preferentially be used in patients with OHS who have sleep hypoventilation without severe OSA. For hospitalized patients with respiratory failure suspected of having OHS, the ATS clinical practice guidelines recommended that patients be discharged on NIV and remain on NIV during sleep until they undergo outpatient workup and titration of PAP therapy in the sleep laboratory, ideally within the first 3 months after hospital discharge (conditional recommendation, very low level of certainty in the evidence).[10]

After considering all the evidence, the TEP recommends that hospitalized patients be discharged on NIV while awaiting outpatient workup. In this situation, the options are to prescribe NIV in the form of BPAP S/T with empiric settings or auto-titrating NIV such as VAPS with the auto-EPAP feature, which has the capability to automatically adjust the respiratory rate to treat hypoventilation can ensure upper airway patency in case of increased resistance (e.g., OSA).

Noninvasive Assessment of Nocturnal Arterial CO_2 Tension

Assessment of $PaCO_2$ is essential for evaluating the adequacy of ventilation in patients receiving NIV. To date, repeat ABG sampling remains the gold standard test. However, besides discomfort, repeat awake ABG sampling does not reliably assess control of nocturnal hypoventilation. While awake, a normal morning $PaCO_2$ level does not actually reflect the abnormal time course of $PaCO_2$ during the night. In these cases, nocturnal noninvasive assessment of $PaCO_2$ by $TcPCO_2$ is an acceptable alternative.

Despite potential technical limitations, continuous $TcPCO_2$ recordings have shown good agreement with arterial measurements. $TcPCO_2$ monitoring also correlates well with ABG in adults requiring NIV for acute respiratory failure, even in those with obesity. Kelly et al[89] found an average difference of 6.1 mm Hg between the $TcPCO_2$ and ABG when analyzing $PaCO_2$. However, this close correlation was diminished with higher $PaCO_2$ levels, specifically those higher than 60 mm Hg. Janssens et al[27] showed that, during NIV, $TcPCO_2$ recordings could be continuously performed for 8 h without any local discomfort or significant signal drift.

The American Academy of Sleep Medicine (AASM)'s clinical practice guidelines for adjustment of NIV in stable chronic alveolar hypoventilation syndromes states that "during attended NIV titration, gas exchange can be monitored by pulse oximetry and the arterial PCO_2 may be measured intermittently by ABG testing or continuously estimated by transcutaneous PCO_2 or $EtPCO_2$ monitoring to allow precise documentation of an adequate level of NIV support."[90] Therefore, we recommend following $TcPCO_2$ as a noninvasive alternative to ABG to determine the presence of alveolar hypoventilation and its response to PAP therapy at the levels provided earlier in this document.

Revised Policies for Hypoventilation Syndromes

The existing coverage criteria for BPAP devices do not recognize the diversity of disorders that constitute hypoventilation syndromes, the variability in acuity and severity of presentation of hypoventilation syndromes over time, and advances in technologies. This results in regulatory barriers to appropriately support patients with hypoventilation syndromes, and these limitations are discussed below.

The current coverage criteria rely on an ABG (criteria A) as the gold standard for assessing hypercapnia. An ABG also helps to differentiate acute, chronic, and acute-on-chronic hypercapnia and provide valuable information as to the possible cause. Yet, access to ABG is not always readily available, especially in the sleep/pulmonary clinic or sleep laboratory. Practical limitations exist to ABG monitoring during sleep, including concern as to whether the pain or anxiety induced by an arterial puncture leads to transient hyperventilation, which, in turn, normalizes $PaCO_2$. Furthermore, in patients with morbid obesity, obtaining an ABG value can be technically difficult and, as such, the patients may decline repeat ABG testing.

For these reasons, interest is growing in noninvasive measures to determine the $PaCO_2$, especially when frequent or continuous monitoring is required. There have been significant technologic advances in surrogate measures of $PaCO_2$, including $EtPCO_2$ and $TcPCO_2$ monitoring. The AASM recommends use of $PaCO_2$, $TcPCO_2$, or $EtPCO_2$ for detection of sleep hypoventilation. Based on data that normal individuals rarely have a $PaCO_2$ value >55 mm Hg during sleep, the AASM revised its scoring of sleep hypoventilation in adults in 2012 to include two criteria: (1) an increase in $PaCO_2$ >55 mm Hg for >10 min or (2) an increase in $PaCO_2$ >10 mm Hg during sleep in comparison to awake supine values to a value >50 mm Hg for >10 min.[91] By relying solely on ABG, the current policies fail to acknowledge the technologic advances made since the 1998 consensus conference and do not allow use of the updated AASM scoring criteria for diagnosing sleep hypoventilation. These surrogate PCO_2 measures are sufficient to identify the condition of hypoventilation appropriate for treatment in patients with HS. This differs from the necessarily more exact $PaCO_2$ ABG threshold to fulfill the conditions consistent with the current scientific evidence supporting treatment for COPD patients. [92]

Technological advances extend beyond CO_2 monitoring to include increasingly sophisticated adherence data from PAP devices and rapidly evolving home sleep testing and consumer sleep technologies, among others. While research on the exact role of these individual technologic developments in both the diagnosis and management of hypoventilation syndromes continues to evolve, coverage criteria need to acknowledge and keep pace with the rapidly developing technologies.

Another challenge to the current BPAP coverage criteria in treating hypoventilation syndromes is the requirement for spirometry (criterion B). This is the only diagnosis category requiring this procedure as mandatory testing rather than clinical judgment. Spirometry may not always be readily available or possible, thereby resulting in delayed treatment. In addition, while some pulmonary measurements like functional residual capacity and expiratory reserve volume decrease with increasing BMI, spirometric variables are rarely below the normal range. In effect, the current requirement for the FEV_1 value to be ≥50% predicted excludes

hypoventilation syndromes caused by more severe parenchymal lung disease that do not fall under other categories and that may benefit from NIV, including patients awaiting lung transplantation.

Hypoventilation often coexists with hypoxemia, but the administration of supplemental oxygen in hypoventilation syndromes has the potential to worsen hypercapnia by various mechanisms. The current BPAP coverage criteria inappropriately force use of oxygen therapy on patients with OHS due to the existing challenges in meeting current BPAP coverage criteria, thereby potentially perpetuating misdiagnosis, delaying appropriate treatment, and even worsening hypercapnia. As recommended elsewhere, there is a need to discontinue current requirements to perform testing on the patient's prescribed supplemental oxygen.

Applying a narrow set of coverage criteria to a heterogeneous group of diseases presenting with variable acuity and severity even within the same patient has limitations. As an example, OHS can present as decompensated acute-on-chronic hypercapnic respiratory failure requiring hospitalization and even an ICU level of care. At the other end of the spectrum, the patient with OHS can routinely present to the outpatient sleep clinic with compensated chronic daytime hypoventilation. Sleep hypoventilation typically precedes daytime hypoventilation in hypoventilation syndromes. Therefore, even within the same disorder and patient, the degree of ventilatory support needed and the optimal DME required for providing this support can vary over time. We recommend continued coverage for the second 90-day compliance assessment period, as noted elsewhere in this document.

Vignette: A 68-year-old severely obese (BMI 65 kg/m^2) woman and lifelong never smoker (no COPD suspicion) is hospitalized with shortness of breath. Her VBG value shows a pH of 7.20 and $PaCO_2$ of 80 mm Hg. She is admitted to the ICU. After 24 h of NIV, the patient improves and NIV is weaned off. At time of transfer to the general medicine ward, her ABG value is pH 7.34, $PaCO_2$ is 60 mm Hg, and PaO_2 is 80 mm Hg on 3 L/min of oxygen. To minimize the risk of rehospitalization, long-term mortality, and prescribing NIV at discharge, the medical team would need to qualify this patient for home BPAP S/T (E0471). Due to the current qualification barriers outlined below, the patient was ultimately discharged without a BPAP S/T and, because of transportation issues due to severe obesity, she missed the sleep clinic appointment. She was readmitted to the hospital with acute-on-chronic hypercapnic respiratory failure 4 months after discharge and, this time, discharged on a costlier HMV using an alternative coverage pathway.

Barriers that failed to qualify this patient for BPAP S/T (E0471) based on current coverage criteria include:

1. "Trial of BPAP device without a backup rate should fail to qualify for one with backup rate," which may increase the length of hospitalization because inpatient NIV is commonly needed with a backup rate to prevent respiratory decompensation.
2. "Spirometry is needed to rule out COPD," which is not widely available as an inpatient test and arguably not necessary for a low clinical suspicion for COPD.
3. "Repeat ABG during or immediately after sleep is needed to demonstrate a higher Pa_{CO_2} than the ABG used to qualify her for a BPAP without a backup rate," but this measurement technique produces sleep fragmentation, pain, anxiety, and possible false results due to resultant hyperventilation.
4. Alternatively, without an ABG (point 3), she would need a "facility-based PSG or home sleep test to rule out OSA as cause of sustained oxygen desaturations." However, many institutions do not have the capability of sleep studies in hospitalized patients and results are often compromised by inpatient sleep patterns and medications; thus, waits for outpatient PSG testing can be 2 to 3 months.

Summary of New Recommendations

Hypoventilation

Item/Service Description

NIV is achieved using a device capable of bilevel pressure delivery (i.e., different pressures during inspiration and expiration). NIV devices may have the option of a backup rate, which ensures a minimum respiratory rate.

Clinical Indications

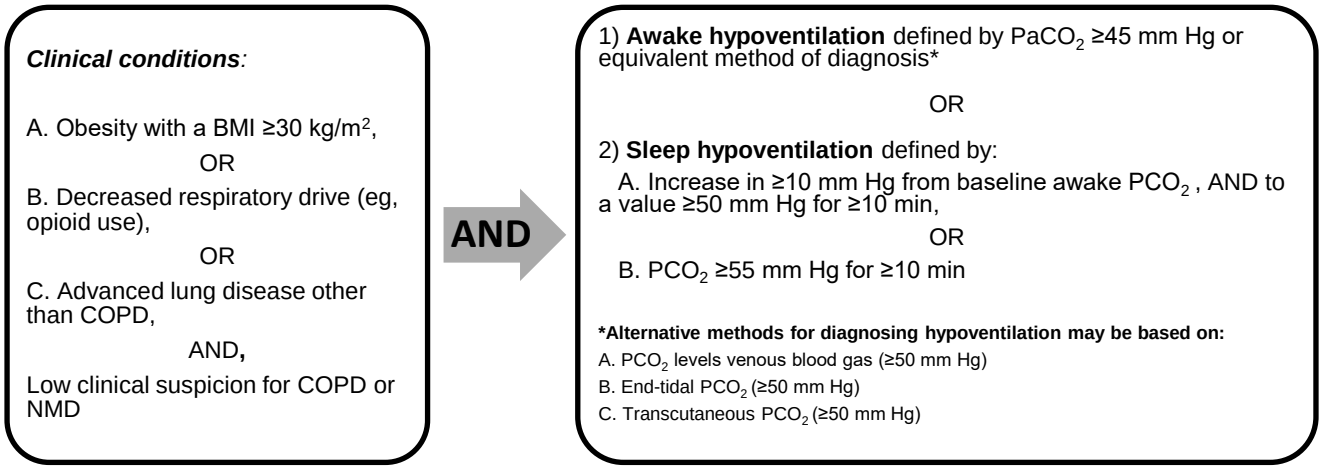
HIV is indicated for hypoventilation syndromes, as defined by an elevated P_{CO_2} value in arterial or venous blood, or elevated P_{CO_2} values measured by Tc_{CO_2} or Et_{CO_2} methods.

This covers the following clinical conditions:

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

Clinical conditions related to hypoventilation are shown in Figure 5.

Figure 5. Definitions of clinical conditions related to hypoventilation.



Indications for Outpatient NIV Support for Hypoventilation Conditions

A. **Obesity-related hypoventilation**

- **<u>Hospitalized patients with persistent awake hypoventilation at the time of discharge</u>** after an episode of acute-on-chronic hypercapnic respiratory failure. *(J96.22: Acute and chronic respiratory failure with hypercapnia)* should receive BPAP ventilation *with* back-up rate (BPAP S/T or VAPS- E0471).
  - For ongoing coverage of equipment, reassessment with a provider within 3 months is required and an attended PSG should be performed to assess appropriateness of the PAP modality.
  - Unattended type 2-4 portable sleep apnea testing is not recommended in patients with hypoventilation but is acceptable if an attended PSG is not obtainable.

- **<u>Ambulatory obese patients with awake- or sleep-related hypoventilation and without severe OSA (defined as apnea-hypopnea index [AHI] or respiratory disturbance index [RDI] <30 events/h)</u>**, ideally based on an attended PSG should be started on BPAP S/T or VAPS- E0471).
  - For ongoing coverage of equipment, follow-up care with a provider within 3 months is required to assess response to therapy and assess appropriateness of the PAP modality.
  - Home sleep testing is not recommended in patients with hypoventilation but is acceptable if an attended PSG is not obtainable.

- **<u>Ambulatory obese patients with wake- or sleep-related hypoventilation and with severe OSA (defined as AHI or RDI ≥30 events/h)</u>** based on attended PSG or home sleep testing should be started on CPAP or auto-CPAP therapy (E0601).
  - Patients who are intolerant or proven ineffective with CPAP may engage the protocol recommended by the "failed CPAP" TEP.
  - If the patient with OHS remains hypercapnic (awake $PaCO_2$ ≥45 mm Hg or PCO_2 ≥50 mm Hg on VBG, $EtPCO_2$, or $TcPCO_2$ despite adequate adherence to CPAP [E0601] or BPAP S [E0470] after 3 months), 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 (e.g., 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** (e.g., end-stage/advanced ILD) should be considered for BPAP S/T or VAPS without the need of sleep testing.

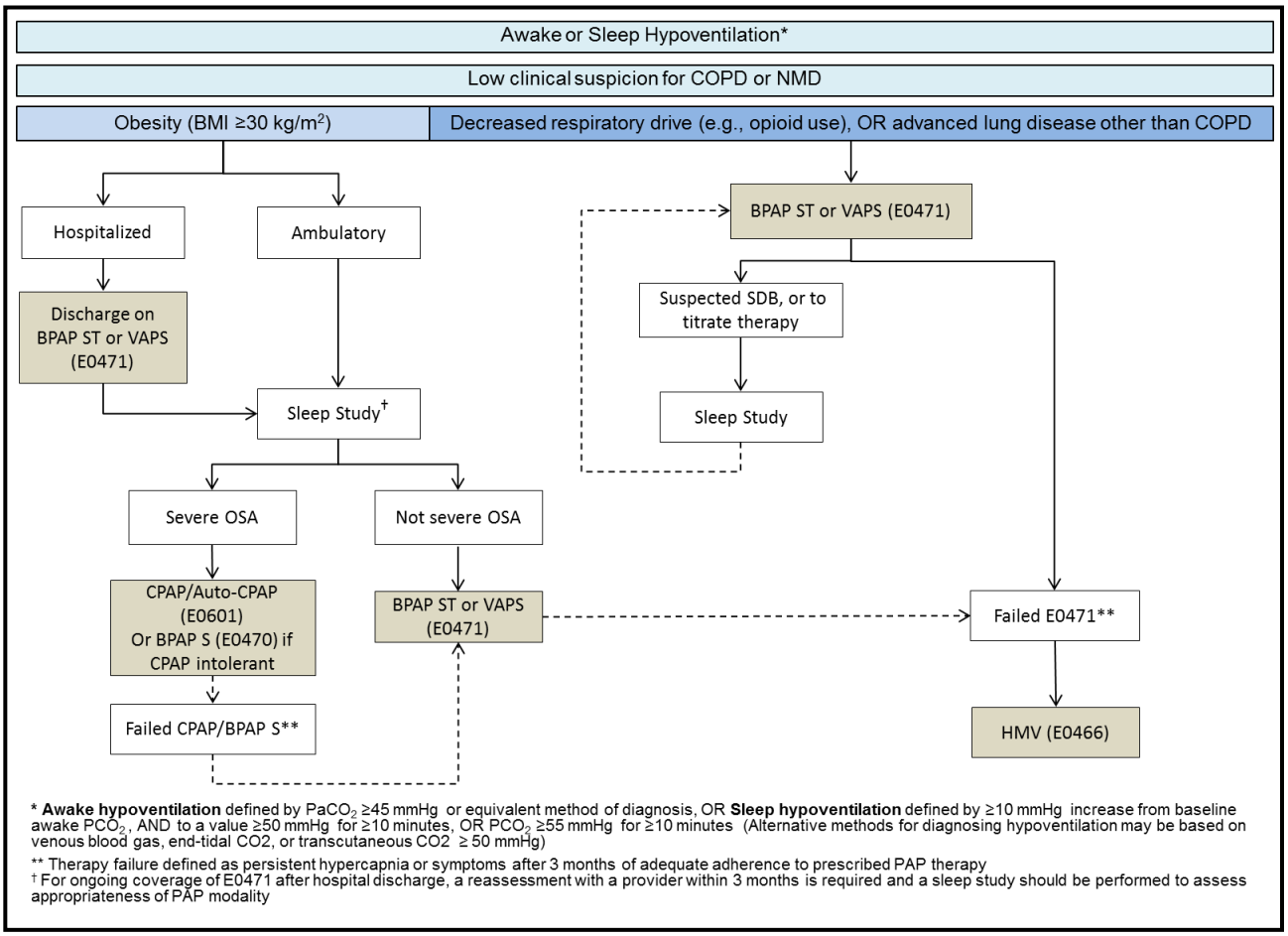
- Sleep testing may be considered if concomitant sleep apnea is suspected or for titration of NIV.

Noninvasive ventilation via an HMV (E0466) is recommended for patients with hypoventilation who need:

- Higher pressures than those deliverable by E0471
- FIO_2 >0.40, which is greater than can be supplied by E0471
- Need for bilevel modes with auto-adjusting EPAP capability (when not available in nonventilator devices such as VAPS E0471) in patients with hypoventilation syndromes when presence and/or severity of OSA are unknown at time of device prescription
- Need for daytime ventilation
- Severe disease in need of a device with alarms, in need for backup ventilator with batteries, or inability to apply or disengage mask without assistance
  - History of at least two hospitalizations for hypercapnic respiratory failure (J96.02) or persistent hypercapnia as defined by $PaCO_2$ value ≥45 mm Hg (or surrogate PCO_2 measurements ≥50 mm Hg) despite adequate adherence to BPAP S/T therapy

This is summarized in graphic form in the flow diagram in Figure 6.

Figure 6. Flow diagram for NIV support for hypoventilation patients.



Supplemental Oxygen Therapy With NIV

- Oxygen supplementation should be adequate to achieve SpO_2 88% to 92% in all causes of chronic hypercapnic respiratory failure after optimization targets of NIV settings, as determined by the treating physician, are achieved.

CENTRAL SLEEP APNEA

Introduction

Central sleep apnea (CSA) is characterized by repetitive transient instability of respiratory drive, resulting in repetitive lessening in ventilatory effort during sleep, in turn leading to apneas, hypopneas, and hyperpneas.[93] Central apneas are identified by diagnostic devices that record

absence of airflow while there is little or no movement of respiratory muscles; by contrast, during obstructive apneas, the respiratory muscles are active. Alternating patterns of apneas or hypopneas followed by hyperpnea occur in about one-third of patients with heart failure (termed CSA with Cheyne-Stokes breathing), during excursion to high altitude (CSA due to high altitude periodic breathing), and, rarely, without any accompanying disease (known as idiopathic or primary CSA).[93] Medical disorders such as brainstem lesions may directly impair ventilatory control neurons and lead to CSA. CSA also occurs acutely in 5% to 15% of patients with OSA when treatment restores pharyngeal patency (termed treatment-emergent CSA [TECSA] or complex sleep apnea (CompSA).[94] CSA may occur in patients using opioids and may follow either a periodic or more ataxic pattern (CSA due to a medication or substance).[95] CSA also may occur in the presence of other respiratory or sleep-related breathing disorders such as congenital central hypoventilation syndrome and in patients with myopathies. It is worth noting that many patients have features of both OSA and CSA during a single night or within individual respiratory events, and it may be challenging to differentiate the underlying mechanism. CSA causes poor sleep quality and adverse effects on cardiovascular health. CSA is associated with symptoms including but not limited to insomnia, frequent awakenings, snoring, witnessed apneas, nonrestorative sleep, hypersomnia, and nocturnal dyspnea.[96]

Moderate to severe CSA is associated with increased mortality in patients with heart failure with reduced ejection fraction (HFrEF). In a recent prospective study evaluating 963 patients with chronic stable HFrEF, those with moderate to severe CSA had almost 20% higher mortality rates than those without sleep-disordered breathing after adjusting for multiple clinical variables.[97] In another prospective study of 88 patients with HFrEF, the median survival rate of patients with CSA was 45 months compared to 90 months of those without CSA (hazard ratio 2.14; $P = .02$).[98] Other studies generally suggest a worse prognosis associated with CSA in heart failure.[99]

The morbidity and mortality associated with CSA may vary greatly depending on the underlying cause. CSA has also been associated with higher disability or mortality in patients with stroke and transient ischemic attacks.[100] CSA at high altitude impairs sleep quality, but it mostly resolves with acclimatization or descent. In a population-based study of primary central sleep apnea, 24% of patients died during a median population follow-up duration of 4.4 years. This high mortality rate may reflect unrecognized cardiac or neurological comorbidities not known at the time of diagnosis.[101] The prognostic implications of CSA on patients chronically using opioids are unknown.

Current Coverage Policies[2]

An E0470 or E0471 device is covered when, prior to initiating therapy, a complete facility-based, attended PSG is performed documenting the following (A and B):

A. The diagnosis of CSA or CompSA; and

B. *Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the beneficiary's prescribed FIO2.*

If all of the above criteria are met, either an E0470 or an E0471 device (based upon the judgment of the treating practitioner) will be covered for beneficiaries with documented CSA or CompSA for the first three months of therapy.

If all of the above criteria are not met, then E0470 or E0471 and related accessories will be denied as not reasonable and necessary.

Problems With Current Coverage Criteria

Although they serve many patients with CSA, the current policies may be a barrier to effective treatment in several circumstances. As exemplars, coverage is not possible for these kinds of patients described in the vignettes that follow.

Vignette: A 67-year-old patient presents with symptoms of frequent awakenings at night and spousal observations of frequent apneas. PSG shows CSA with central AHI (CAHI) of 11, obstructive AHI (OAHI) of 7, and frequent awakenings. On CPAP 8 cm H_2O, CAHI is 6, OAHI is 1, and sleep continuity is much improved. Idiopathic CSA is diagnosed. *The current policies do not allow CPAP coverage for this patient*.

Vignette: An 84-year-old patient with severe heart failure and ejection fraction of 35% has significant symptoms, including disrupted sleep. PSG demonstrates CSA with Cheyne-Stokes breathing and an AHI of 30/h. Mean SpO_2 is 93%, and the minimum is 87%. SpO_2 is ≤88% for 3.5 min and sporadic. The patient is diagnosed with CSA. Breathing does not improve on PAP or PAP is poorly tolerated. On oxygen 3 L/m via nasal cannula without a PAP device, no apneas are present, and the arousal index is decreased by 75%. *The current policies do not allow oxygen therapy for this patient.*

Vignette: A 76-year-old patient with a history of stroke complains of severe sleepiness. During PSG, the CAHI is 20 and the OAHI is 30 events/h. CPAP is titrated during an attended PSG. As the pressure increases, the CAHI rises and the OAHI falls. The best setting on CPAP still yielded a CAHI of 30 and the OAHI was 9 events/h. The patient is diagnosed with complex CSA. BPAP is titrated on a separate night, and the response is similar. BPAP S/T is titrated on a third night. At best pressure, the CAHI is 4 and the OAHI is 6 events/h, and higher pressures were poorly tolerated by the patient. There is significant objective and subjective improvement on BPAP S/T. *The current policies do not allow BPAP ST therapy, because the OAHI was above 5/h on CPAP and BPAP. The current policy indicates that a BPAP-S/T or adaptive servoventilation (ASV) device may only be covered if CSA remains despite "obstructive AHI less than 5/h."*

Vignette: A 69-year-old man has severe treatment-emergent CSA and congestive heart failure with an ejection fraction of 65%. He has been using BPAP S/T for 13 months, but he still has a high AHI, persistent sleepiness, insomnia. Using ASV during a repeat attended PSG, the AHI is improved, and the patient has improved sleep quality. *The current policies do not allow for ASV therapy for 5 years because another E0471 has been previously covered.*

Current Evidence/Clinical Consensus Practice Guidelines

Relatively few studies exist of outcomes after CSA therapy, but clinical experience and early data support CSA therapy to improve symptoms and perhaps to improve outcomes.[93] The CANPAP study, a randomized trial of CPAP therapy for CHF with Cheyne Stokes breathing, did not find a major benefit to CPAP therapy compared to medical treatment, but some post hoc analyses suggested better outcomes in patients who respond to CPAP intervention.[102,103] Some studies showed improvement in ejection fraction with ASV therapy in congestive heart failure, and clinical practice repeatedly demonstrates that some patients with CSA report markedly improved insomnia, fatigue, and other symptoms while on ASV therapy.[104] By contrast, the Serve-HF study demonstrated potential for harm when CHF patients with HFrEF and Cheyne-Stokes breathing were treated with ASV therapy.[105] Ongoing trials using different ASV treatment algorithms are designed to further examine the role for this therapy in patients with optimized medical therapy.

Opioid-induced CSA is more frequent and more severe at higher narcotic doses, and clinical experience has shown that ASV therapy for CSA may improve breathing patterns, sleep continuity, pain, and may contribute to opioid weaning.[95]

Most treatment-emergent CSA resolves spontaneously, but randomized trials have shown that treatment of the CSA component is associated with improved PAP adherence for OSA therapy.[106] Switching from CPAP to ASV may be associated with abrupt improvements in residual apnea and in adherence at the time of switching.[107] Data in this area are evolving, but it is already clear that ASV is an important therapy for patients with persistent TECSA. Sleep-transition CSA usually resolves without intervention. Idiopathic CSA is often treated with CPAP, BPAP-S/T, or ASV without a strong evidence base.[108]

Oxygen treatment may be effective in CSA from any of the above causes.[109] High-altitude periodic breathing appears to respond better to supplemental oxygen than to ASV therapy.[110] Clinically, some patients are intolerant of BPAP therapy respond well to oxygen therapy.[93]

We expect ongoing studies to clarify the best CSA treatments for long-term outcomes. Until then, clinicians individualize therapy with CPAP, BPAP S/T, ASV, and supplemental oxygen to

achieve PSG evidence of stabilized breathing patterns, improved blood oxygenation, and better sleep continuity as well as to achieve symptomatic relief. Coverage determinations should allow therapy based on best current practices.

Revised Policies for CSA

The current policies were developed over the last 20 years, during which time the understanding of CSA pathophysiology, responses to treatment, and device technology has changed. The above cases exemplify situations in which modifications to the current policies must allow better medical management for these patients. We view that the main areas requiring modification are: (1) the definition of CSA to bring it into harmony with current clinical definitions, (2) to precisely state the sleep testing required to diagnose CSA, (3) to create coverage for PAP devices, oxygen therapy, or both that provide clinical benefit, and (4) to harmonize ongoing coverage criteria with those of OSA rather than with diseases with hypoventilation.

Definition of CSA

As previously stated, current policies separately define *CSA* and *complex sleep apnea*. Treatment options may be similar for each of these disorders, and the distinct definitions do not always add clarity or clinical value. One issue is that the policies require that a patient with CSA must have an OAHI <5, which is inconsistent with definitions of current CSA or complex sleep apnea/TECSA. Some patients with CSA continue to have an OAHI <5 at optimal tolerated treatment pressures. As treatment pressure rises, central events may predominate, and, at times, finding an ideal pressure that eliminates obstructive events worsens central events.

RECOMMENDATION: Revised policies should adopt a single definition of CSA that aligns with accepted society definitions, with CSA predominance without necessitating resolution of obstructive events.

RECOMMENDATION: Qualifying symptoms for CSA therapy should parallel the symptoms that qualify a patient for OSA therapy and be generalized to prevent frivolous rejection of prescriptions based on unlisted specific symptoms.

Criteria for all types of CSA (patients must meet both A and B):

A. AHI criteria: A polysomnogram or a sleep study that measures airflow and respiratory muscle movement or that is otherwise validated as a diagnostic test for CSA, must demonstrate:

1. A central apnea-hypopnea index (CAHI) is greater than or equal to 5/hour AND

2. The sum of central apneas and hypopneas is ≥ 50% of the sum of all apneas and hypopneas AND

B. Symptom criteria:

1. *Patients with an AHI ≥ 5 and < 15 should demonstrate symptoms or impairments in sleep-related quality of life (**including but not limited to** excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, excess fatigue/decreased energy/vitality, nocturia, sleep-related choking, morning headaches, restless sleep, impairments in productivity or social functioning), OR*
2. *Patients have an AHI ≥ 15*

RECOMMENDATION: Because BPAP without a backup rate typically worsens CSA,[111] revised policies should not require a BPAP (without backup rate) trial before E0471 coverage is accepted.

The current definition of CSA requires that "there is no evidence of daytime or nocturnal hypoventilation." However, the policy later requires "significant improvement of the sleep-associated hypoventilation." Presumably, hypoventilation is thus used in two ways in the current policy, i.e., one referring to sustained retention of CO_2 and the other referring to hypopneas. This does not add clarity or value.

RECOMMENDATION: Hypoventilation should not be referred to in the section on CSA.

Coverage Criteria for PAP Devices and/or Oxygen Therapy That Provides Clinical Benefit
In a minority of patients, CPAP, oxygen, or both provide significant improvement in CSA,[108] and these treatments are recommended in clinical guidelines. Unfortunately, the current coverage determinations do not cover CPAP (E0601) or oxygen therapy for patients with CSA.

RECOMMENDATION: Allow CPAP as therapy for CSA when it is shown to be effective.

RECOMMENDATION: Allow oxygen therapy for CSA when it is shown effective for an individual patient during sleep testing in either of the following situations:

1. Altitude-related periodic breathing that is shown to reduce the AHI and result in clinical improvement with oxygen therapy
2. CSA with cumulatively ≥5 min SaO_2 ≤88%
3. CSA persistent on CPAP or E0471 device without sustained hypoxia but oxygen (either in addition to PAP or alone) is shown to lead to clinical improvement, such as improving sleep quality or reducing the CAHI <10
4. CPAP or E0471 is not tolerated or is contraindicated, and oxygen alone is shown to lead to clinical improvement, such as improving polysomnographic sleep quality, bring the SaO_2 ≥88%, or CAHI <10

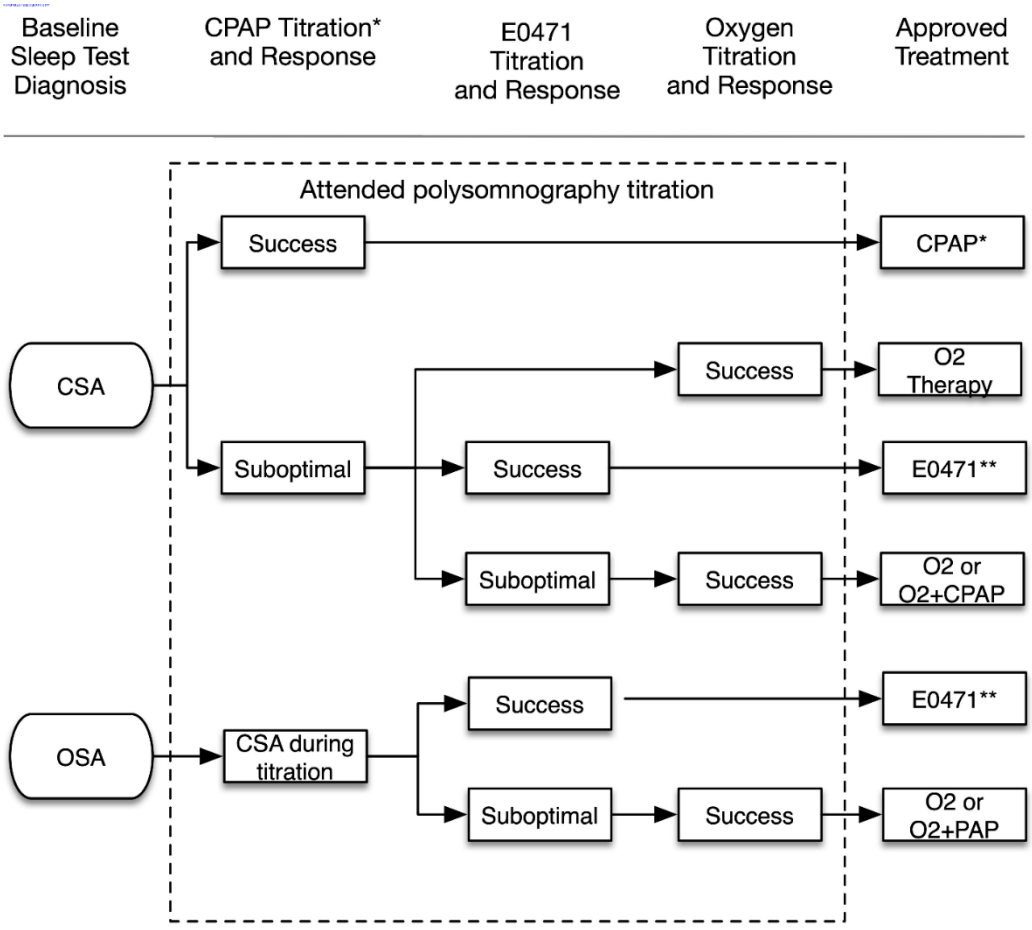
E0471 devices operate with proprietary algorithms. As a result, some patients respond better to one servoventilation or BPAP with a backup rate device than to another.

RECOMMENDATION: Revised policies should cover treatment with any effective E0471, even if a patient is previously prescribed and using a less effective bilevel device with a backup rate.

Clinical suboptimal responses or improvement with PAP devices or oxygen should be demonstrated during PSG. As is common practice, split night sleep studies or trials of several different treatment modalities during one night of PSG may be appropriate (e.g., when one modality is clearly ineffective after only a short exposure). The current policies require demonstration of "significant improvement" with the device at the setting that is prescribed for initial home use. Because the AHI does not always resolve in CSA even when oxygen saturations, arousals, and symptoms improve, significant improvement should include measures of improvement other than the AHI based on the discretion of the treating physician. A recommended evaluation pathway is shown in Figure 7.

Figure 7. Recommended evaluation pathway for determining appropriate treatment of CSA syndrome.

For patients starting with who have a



Suboptimal responses to CPAP or E0471 must be demonstrated by attended polysomnography. Titration of CPAP, E0471, and/or O2 may be done during single in-lab study as time allows.
* A BPAP-S may be used instead of CPAP, though usually this has worse results than CPAP
** 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 O2 to E0471 in some cases
CSA = Central Sleep Apnea; OSA = Obstructive Sleep Apnea; E0471 is a bilevel device with a backup rate.

suboptimal response to CPAP (upper pathway), consider oxygen without PAP, an E0471 device (refer to the text) alone, or a combination of PAP plus oxygen. Patients who demonstrate treatment-emergent CSA (lower pathway) may benefit from either an E0471 alone or from PAP plus oxygen. If they are technically acceptable, multiple treatments may be tried in a single PSG session.

CSA patients requiring E0471 devices are currently required to have a face-to-face follow-up visit in 61 to 90 days after starting therapy even if documentation of adherence and benefit can be made earlier. There is no clinical reason why delayed evaluation is necessary for this population.

RECOMMENDATION: The policy providing continuing coverage for CSA should include the same criteria as patients with OSA and clinical documentation of benefit can be demonstrated in the same 31 to 90 days as CPAP.

However, consistent with the other TEP category recommendations, 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 before considering alternative therapy.

Summary of New Recommendations

A summary of recommended changes in current coverage determinations, which will improve care in a timely fashion for patients with CSA, are as follows:

- A single definition of central sleep apnea will simplify and clarify coverage decisions.
- The discussion for 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 devices, BPAP devices, and RADs with a backup rate (i.e., E0471), including BPAP S/T, servoventilation, and VAPS, 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 for OSA therapy.

OBSTRUCTIVE SLEEP APNEA

Introduction

OSA is a highly prevalent disorder characterized by repetitive upper airway obstruction during sleep with intermittent hypoxemia and arousals.[112] OSA is associated with adverse effects, including neurobehavioral impairments (e.g., excessive sleepiness, impaired quality of life, fatigue, mood changes), cardiovascular events, metabolic dysregulation, and higher rates of mortality. PAP therapy, including CPAP and bilevel BPAP, remains the most common treatment, regardless of OSA severity. Greater adherence to PAP therapy is associated with improved outcomes and is critical to satisfying current coverage determination policies.[113]

Current Coverage Criteria[4]

In this policy, the term PAP (positive airway pressure) device will refer to both a single-level continuous positive airway pressure device (E0601) and a bilevel respiratory assist device without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea.

I. An E0601 device is covered for the treatment of obstructive sleep apnea (OSA) if criteria A – C are met:

A. The beneficiary has an in-person clinical evaluation by the treating practitioner prior to the sleep test to assess the beneficiary for obstructive sleep apnea.

B. The beneficiary has a sleep test (as defined below) that meets either of the following criteria (1 or 2):

1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
b. Hypertension, ischemic heart disease, or history of stroke.

C. The beneficiary and/or their caregiver has received instruction from the supplier of the device in the proper use and care of the equipment.

If a claim for an E0601 is submitted and all of the criteria above have not been met, it will be denied as not reasonable and necessary.

II. An E0470 device is covered for those beneficiaries with OSA who meet criteria A-C above, in addition to criterion D:

A. An E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.
Ineffective is defined as documented failure to meet therapeutic goals using an E0601

during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings).

If E0470 is billed for a beneficiary with OSA and criteria A-D are not met, it will be denied as not reasonable and necessary.

A bilevel positive airway pressure device with back-up rate (E0471) is not reasonable and necessary if the primary diagnosis is OSA. If an E0471 is billed with a diagnosis of OSA, it will be denied as not reasonable and necessary.

If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not require a new initial in-person clinical evaluation or a new sleep test. If an E0601 device has been used for more than 3 months and the beneficiary is switched to an E0470, a new initial in-person clinical evaluation is required, but a new sleep test is not required. A new 3-month trial would begin for use of the E0470.

Problems With Current Coverage Criteria

The TEP discussions with key stakeholders revealed aspects of LCD 33718 that require updating or remain vague due to newer research and guideline updates.[4] Both providers and DME suppliers have variable interpretations of the current coverage determination policies that can lead to wasteful expenditure of agency resources or needless denials. Furthermore, because of the ongoing COVID-19 pandemic, the unique capability of PAP devices to transmit adherence and effectiveness data has led to the recognition that telehealth can complement or potentially replace in-person visits yet provide high-value health care. Herein, the TEP describes specific patient-provider situations that confound the ability of clinicians to deliver optimal NIV Medicare access with recommendations for improvement of current coverage determination policies.

Initial Coverage

Current coverage determination allows for PAP therapy to Medicare beneficiaries with mild OSA only if certain symptoms and comorbidities are present. Symptoms specifically listed include excessive daytime sleepiness and others such that auditors will strictly adhere only to these. However, many patients with mild OSA experience many other OSA-related symptoms not included in current policies that adversely impair their quality of life and can be excluded from coverage.[4,114] Because it is implicit that the patient comes to their caregiver because they are symptomatic, this “symptom” criteria should be altogether excluded.

BPAP for Patients Intolerant to CPAP

The existing policy allows BPAP if CPAP has been “tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.” Policy specific documentation later defines “tried and proven ineffective” to include documentation of issues related to “interface fit and comfort” and “pressure settings” that failed to adequately control the symptoms of OSA, improve sleep quality, or reduce the AHI or RDI to acceptable levels. However, this may dictate unnecessary clinical efforts and has largely been ignored by

commercial payors and DME suppliers, because mask interface issues are unrelated to determination of BPAP as alternative treatment. In general, based on the TEP discussion, clinicians consider CPAP as "tried and proven ineffective" based on patient self-reporting or by technologist observation in the sleep laboratory of issues, with pressure intolerance, disturbed sleep, failure to correct the AHI/RDI, sleep oximetry, or persistent hypercapnia occurring while using CPAP.

Continued Coverage or Requalification of PAP Therapy Beyond the First 3 Months

The requirements for continued PAP coverage devices beyond 90 days in certain circumstances has created significant problems for Medicare beneficiaries and contributed to wasteful expenditures for additional sleep testing. Currently, CMS requires beneficiaries with OSA to demonstrate adherence to PAP therapy defined by ≥4 h/day for ≥70% of days in a consecutive 30-day period within the first 3 months and an in-person visit with their treating provider that demonstrates that their OSA symptoms are improved for continued coverage. The adherence threshold of 4 h/day, which was based on clinical consensus in the early days of PAP adherence research, is too high for some patients to reach. In particular, those of lower socioeconomic status may be unfairly disadvantaged by this requirement.[114] Evidence reveals that as little as 2 h of therapy per day can benefit Medicare-age patients,[115] suggesting that adherence should be assessed in conjunction with clinical outcomes.[116] Many patients struggle early on with therapy and require multiple mask adjustments, PAP-related desensitization, or other educational, troubleshooting, or behavioral interventions that may take more than 90 days to optimize adherence. Furthermore, some patients are unreasonably "penalized" with the need for additional appointments with their provider even if they are highly adherent but are inadvertently mis-scheduled for a follow-up visit before or after the official 31- to 90-day visit requirement.

Current coverage policies mandate that all beneficiaries with OSA who fail to satisfactorily meet the 90-day adherence guideline must undergo in-person reevaluation and a type 1 sleep study to secure another 90-day PAP trial. Mandating requalification of treatment-adherent beneficiaries who, due to extenuating circumstances (e.g., travel, hospitalization), could not return within the 31- to 90-day window required for the in-person visit is burdensome, expensive, and of dubious benefit. Adherence and efficacy data captured by PAP devices combined with provider visits (in-person or telehealth) may allow for the requisite troubleshooting in patients beyond the 90-day period without requiring an attended, laboratory-based, or home-based sleep study if such patients continue to be engaged with their provider and express interest in continuing to optimize therapy. Those still engaged with their NIV-treating physician who attempt, but do not yet succeed, with the adherence criteria should be allowed another 90-day PAP trial before considering alternative therapy.

Concurrent Use of Oxygen With PAP Therapy

Although PAP therapy is adequate for most patients with OSA, some will have persistent nocturnal hypoxemia due to underlying cardiopulmonary conditions. Current policies on concurrent oxygen use with PAP therapy have resulted in disparate practices in qualifying patients for oxygen and have represented regulatory barriers to optimal patient care.

One of the interpretive challenges has been whether a patient can qualify for supplemental oxygen and PAP therapy during an initial split-night sleep study in which diagnoses of OSA and sleep-related hypoxemia despite PAP therapy are established. Another ambiguity is whether the patient must subsequently demonstrate PAP adherence as an outpatient to be considered in a "chronic stable state," and then undergo retesting to observe if sleep-related hypoxemia persists despite PAP therapy. An affirmative interpretation leaves some patients vulnerable to adverse health outcomes during the PAP-only period. Another challenge has been that some interpret the policy to require that the AHI must be reduced to less than 10 events/h (or below the baseline AHI if it was 5.0-9.9 events/h) on CPAP for a minimum of 2 h during PSG vs just a portion of the 2-h minimum duration of PAP titration. Furthermore, the location and timing of "nocturnal oximetry" documenting hypoxemia on optimal PAP settings are ambiguous.

Beneficiaries Entering Medicare

Many Medicare beneficiaries will receive PAP therapy prior to Medicare enrollment. Current coverage determination policies require that patients who have already received PAP therapy prior to enrollment must provide a diagnostic sleep study demonstrating the presence of OSA and have an in-person evaluation with their treating provider that documents the diagnosis of OSA and continued PAP use by the beneficiary. However, this policy may present a regulatory barrier to appropriate patient care if long-term adherent patients or their treating providers cannot produce a qualifying sleep study from the distant past for a variety of reasons. New beneficiaries who have long been established on PAP therapy are then required to undergo repeat diagnostic sleep testing, thereby resulting in an unnecessary expense for CMS an undesirable retesting burdens (e.g., sleeping without their PAP device for the night or having to stop PAP therapy for two nights prior to the sleep study to ensure OSA severity returns to baseline).

Telehealth

Early in the COVID-19 pandemic, seniors were recognized to represent a vulnerable group for COVID infection, and these individuals disproportionately experience the most severe of COVID outcomes.[117] As a result, most providers have pivoted to providing care via telehealth visits, which was supported under the CMS medical emergency waiver and has been well received by patients and health-care providers alike. The experiences of many providers have demonstrated that both new and follow-up telehealth visits can be successfully utilized but

require similar time and resources to in-person visits. Given recent experiences, current policies should be expanded. The American Medical Association has strongly supported inclusion of virtual visits by proposing resolution 203 on November 17, 2020, stating that it "advocates for equitable access to telehealth services, especially for at-risk and under-resourced patient populations and communities, … and support the use of telehealth to reduce health disparities and promote access to health care."[118]

Current Evidence/Clinical Consensus Practice Guidelines

BPAP for Patients Intolerant to CPAP

Recent clinical guidelines continue to recommend CPAP or autoadjustable PAP over BPAP when initiating treatment for OSA in adults.[113] Nevertheless, current guidelines recognized situations in which patients with OSA may benefit from BPAP therapy. For example, one study examined the potential role of BPAP as rescue therapy after at least 2 weeks of suboptimal adherence while using CPAP.[119] Those randomized to BPAP vs continuing CPAP demonstrated greater nightly adherence to PAP at 3 months, with 49% of the BPAP group compared to 28% of the CPAP group subsequently meeting the CMS definition of adherence. A retrospective study of US veterans, with many of similar age to Medicare beneficiaries, suggested that those initially prescribed BPAP were more likely to be adherent at 30 months.[120] In another study examining BPAP as rescue therapy, patients nonadherent to CPAP at 90 days who were transitioned to auto-BPAP demonstrated improvements in adherence, sleepiness, and sleep-related quality of life at 10 weeks compared to the period of time on CPAP.[121] The available evidence supporting the use of BPAP in OSA indicates that BPAP is an appropriate treatment option for patients with OSA when CPAP has been tried and proven to be intolerable or ineffective.

Defining Symptomatic Patients With OSA

The current coverage policies allow for CMS beneficiaries with mild OSA to obtain PAP, whether CPAP or BPAP, in the setting of several common symptoms associated with OSA; however, the list does not fully encompass the range of symptoms associated with OSA that impair sleep-related quality of life and can be improved with treatment. For example, recent AASM guidelines[113] made a conditional recommendation that CPAP should be used to treat OSA in adults with several symptoms that impair sleep-related quality of life. The AASM recommendation was supported by a meta-analysis of common sleep-related quality of life questionnaires, including the Function Outcomes of Sleep Questionnaire (FOSQ) and the Sleep Apnea Quality of Life Index. One of these studies specifically examined improvements in sleep-related quality of life using the Sleep Apnea Quality of Life Index in adults aged ≥65 years.[115] A subsequent randomized control trial from the United Kingdom demonstrated moderate to large improvements in vitality and fatigue after 3 months of CPAP in mild OSA, with 81% of participants wishing to continue with CPAP.[122] Thus, the available studies indicate that the

current symptom list that qualifies Medicare beneficiaries for PAP in the setting of mild OSA is too limited.

Definitions for Continued Coverage

A critical element of continued coverage for PAP for CMS beneficiaries with OSA is meeting the CMS definition of adherence, which is "use of PAP ≥ 4 hours per night on 70% of nights during a consecutive thirty (30) day period any time during the first three (3) months of initial usage." The basis of the original adherence definition was from a paper examining CPAP use via an objective monitor and was based on expert clinical opinion.[123] However, subsequent studies, including randomized controlled studies,[124-129] indicate that improvement in OSA-related symptoms and outcomes can occur below the CMS threshold and have demonstrated a dose-response relationship. For example, in the PREDICT trial of older adults (**age ≥65 years**), clinically significant improvement in the Epworth Sleepiness Scale (ESS) was observed at 3 months, despite a median adherence of 1 h and 52 min (interquartile range: 19 min to 5 h 12 min).[124] In another study of 150 adults with severe OSA,[116] approximately 20% to 50% of participants using PAP between 2 and 4 h/night demonstrated normalization of the ESS, FOSQ, or multiple sleep latency test, with greater use associated with a greater proportion of the study sample with normalized values. A similar dose-response relationship with measures of ESS and FOSQ was seen in a subsequent study of adults with moderate-severe OSA treated with CPAP.[130]

Furthermore, the CMS requirement to meet the adherence threshold within the first 90 days may disadvantage some Medicare beneficiaries. For instance, some patients may take more than 90 days to reach conventional adherence definitions, as highlighted in one study that demonstrated that 30.4% became adherent for the remainder of the first year after only becoming adherent beyond the initial 90-day period.[131] Other studies suggest that the adherence requirement may, in particular, disadvantage Medicare beneficiaries of lower socioeconomic status and older adults who are eligible for Medicaid.[115] Thus, the current definitions of adherence necessary for continued coverage runs counter to CMS' aim to eliminate disparities in health care quality and access and thus should be revised.

Requalification for PAP

Beneficiaries who fail criteria to qualify for PAP therapy in the initial 90-day period have a pathway to requalification. Consensus exists within the TEP panel that patients "fail" PAP therapy for a wide variety of reasons. Factors for nonadherence or nonresolution of OSA-related symptoms can in most instances be determined through careful evaluation by the treating provider to address issues such as underlying sinus or nasal condition, changing masks, adjusting pressure settings, switching PAP modes, or even considering alternative diagnoses. In most instances, a facility-based type 1 sleep study should be optional, but not mandated, for

requalification of PAP therapy coverage. Furthermore, if further sleep testing is deemed necessary, then the type of test, facility-based or home-based, should be at the discretion of the treating provider.

Revised Policies for Obstructive Sleep Apnea

Based on the data reviewed above, the TEP recommends CMS revise current policies as indicated below (see Figure 8 for the revised pathway).

Policy for Initial Coverage

The coverage determination policy should continue to provide initial coverage for patients diagnosed with moderate to severe OSA. However, initial coverage of a PAP device (E0601 or E0470) for mild OSA should be revised to allow coverage for:

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 conditions such as hypertension, ischemic heart disease, or history of stroke

Bilevel PAP for Patients Intolerant to CPAP

The current criteria should continue because it provides appropriate coverage to beneficiaries for an E0470 when "an E0601 device has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting."[4] The details of the intolerant and/or ineffective CPAP response should be documented in the patient record, but the specifics should be determined by the treating practitioner.

Policy for Continued Coverage

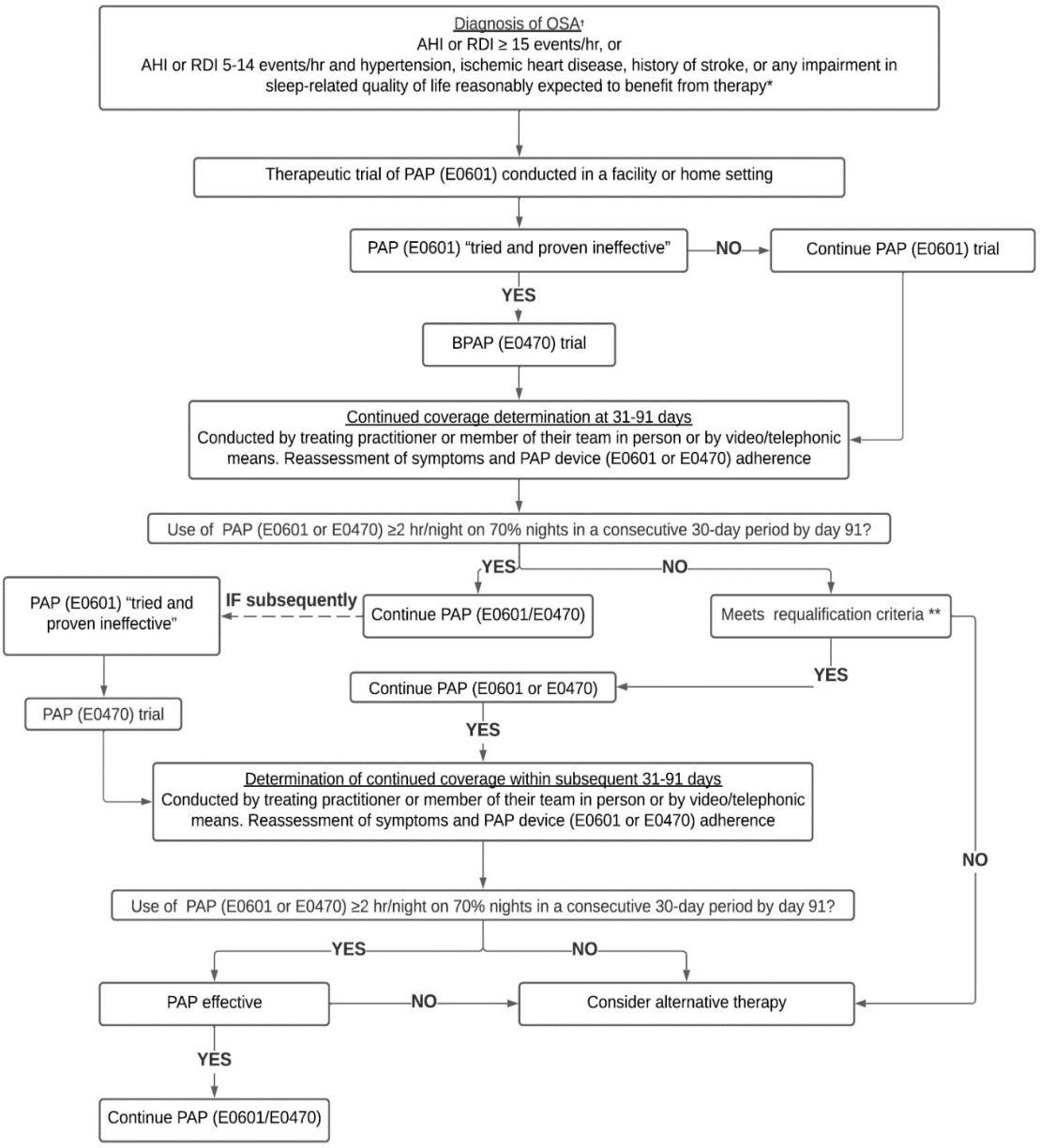
The coverage policy regarding continued coverage for either PAP device (E0601 or E0470) should be revised to:

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

Figure 8. Revised policy algorithm for OSA.

Requalification for PAP

The revised coverage determination policy should include the following to requalify for PAP therapy:



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

*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

**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

- The treating practitioner will re-evaluate and document the reason the beneficiary has suboptimal PAP therapy adherence and the reason for reconsidering the treatment of OSA with PAP.
- The need for additional sleep testing should be at the discretion of the treating practitioner, rather than mandatory, and may be either home- or facility-based.
- If use and/or benefits have not been reached during a subsequent 90-day period, then alternative treatments should be considered.

Beneficiaries Entering Medicare

- Beneficiaries newly enrolling in Medicare with OSA currently using PAP therapy should not be denied coverage based on absence of documentation of a prior diagnostic sleep study demonstrating OSA or the in-person assessment for OSA by the provider required within 6 months of the initial diagnostic sleep study. Coverage should be continued if the treating practitioner (or designee) has conducted a clinical reevaluation within 6 months of an order for a replacement PAP device or supplies and documented that the beneficiary was benefitting from PAP therapy based on meeting the previously defined adherence criteria and improvement in OSA-related symptoms.

Concurrent Oxygen With PAP

Although the TEP recognizes that the concurrent use of oxygen with PAP is outside of the coverage policy for BPAP, it is important to comment on potential revisions needed for optimal care given the wide regional variation in implementation of current policies by the DME MACs and DME providers. The TEP recommends the following revisions to coverage determination policies:

- For beneficiaries to be considered in a chronic stable state, adequate treatment of OSA should be defined as an AHI ≤10 events/h or a 75% reduction from the baseline AHI either:
  - During a PAP titration PSG with ≥2 h of the titration portion; or
  - Based on a concurrent domiciliary oximetry AND PAP report
- Coverage criteria for supplemental oxygen is achieved if during the PAP titration PSG or concurrent domiciliary oximetry and PAP reports:
  - The oxygen saturation remains ≤88% for a total of 5 min (noncontinuous); and
  - Adequate PAP treatment as above is achieved

Telehealth Provision

To enhance access to the highest quality care and build on the experiences gained from the COVID pandemic, the TEP recommends that all required face-to-face reevaluations for CMS beneficiaries with OSA after initiation of PAP therapy may also be accomplished by video/telephonic means.

Recommendations for Other Areas CMS Should Consider Addressing

The TEP also identified additional areas of the coverage determination policy that have overlap with other policies and should be considered for updates and revisions. A summary and recommendations follow:

- **Hypopnea definition:** The policy for PAP therapy coverage for OSA defines hypopneas as a 10-s event with a minimum 30% decrease in thoracoabdominal effort or airflow and a ≥4% decrease in oxygen saturation. The CMS definition stands in contrast to the definition used by most clinicians that defines hypopneas based on either a 3% oxygen desaturation or an arousal from sleep.[132] Research suggests similar associations of this consensus definition as the CMS hypopnea definition with OSA-related outcome, including cardiovascular and cerebrovascular disease, quality of life, daytime sleepiness, occupational and motor vehicle accidents, metabolic disease, and mortality.[133] The TEP strongly recommends that CMS reevaluate the hypopnea definition to identify those who will benefit from treatment.
- **Definitions of RDI and AHI:** Current CMS use of the terms *AHI* and *RDI* do not conform to definitions used by clinicians. The RDI is used by CMS to refer to sleep apnea severity based on home-based testing, whereas standards set by national organizations use this term to include apneas, hypopneas, and respiratory-effort related arousals.[133] Currently, the term *respiratory event index* has been recommended to reflect sleep apnea severity determined based on monitoring time, because some home-based tests, which assess sleep time, can determine an AHI or RDI.
- **Orphan diagnoses where PAP is beneficial:** The TEP also identified patients with disorders other than sleep apnea who may benefit from PAP therapy due to its ability to act as an airway stent. These include disorders such as tracheobronchomalacia with excessive dynamic airway collapse, multisystem atrophy in which patients may develop nocturnal stridor, and other similar disorders. CMS beneficiaries with these disorders are denied PAP therapy unless they meet coverage determination policies for OSA, yet many clearly benefit from PAP therapy and need an appropriate pathway to obtain symptomatic relief.

Summary of New Recommendations

- Documentation by the clinician that CPAP was “tried and proven ineffective” and the patient specific issues with CPAP treatment should be considered sufficient for BPAP.

- For patients with mild OSA, any impairment in sleep-related quality of life that in the judgment of the treating physician may be expected to benefit from therapy should be afforded initial coverage.
- Patients with OSA can have improvements in quality-of-life symptoms with as few as 2 h of PAP use during sleep daily. In addition, many patients have initial challenges meeting a 4-h/night goal; therefore, adherence criteria should be redefined as use of PAP ≥2 h/night on 70% of nights during a consecutive 30-day period any time during the first 3 months of initial usage. Patients who do not meet these criteria within the first 3 months may only requalify if they meet requalification criteria.
- Patients who have not met continuing coverage criteria should be allowed to requalify under certain circumstances. Specifically, these patients may qualify after a reevaluation with the treating practitioner who documents the etiology of the failure to respond to PAP therapy and consideration of alternative treatments for OSA. The treating practitioner should document the reasons for an additional trial of PAP, and the need for additional sleep testing should be at the practitioner's discretion.
- Telehealth should be continued as an alternative for patient assessment and monitoring response to therapy.
- Supplemental oxygen with PAP criteria should be simplified to demonstrating adequate treatment of OSA (AHI <10 events/h or a 75% reduction from the baseline AHI either during a PAP titration PSG in which the entirety of the titration portion is ≥2 h or based on concurrent domiciliary oximetry and PAP report). Coverage would be provided if, during the PAP titration, PSG or concurrent domiciliary oximetry and PAP reports the oxygen saturation remains ≤88% for a total of 5 min (need not be continuous) and adequate PAP treatment is achieved.

RIGHT DEVICE FOR THE RIGHT PATIENT AT THE RIGHT TIME

As CMS reviews the recommendations in the NCD request, it is imperative to keep in mind that the delivery of NIV in the home is incumbent upon all participants working together toward the goal of making sure the patient gets the right device for the right reason at the right time. This includes the manufacturers, physicians, clinicians, respiratory therapists, suppliers, and the patient and caregivers.

We believe the clinical recommendations in our request for a new NCD will remove limitations on reasonable and necessary treatments for beneficiaries receiving bilevel ventilation or HMV that have resulted in unnecessary or inappropriate utilization in the past. These recommendations also give clinicians more options to provide the best course of treatment for

their patients. However, to achieve these goals, it is necessary that the NCD clearly indicate that contractors should evaluate the criteria using the prescribing clinician's prescription and, if necessary, templates and clinician attestations. Given the complexities of the medical record and differing clinician documentation preferences, medical record review is not optimal and should be avoided to provide uniformity and certainty, while avoiding inconsistencies, in the review of individual claims.

Recommendations

- Eliminate medical record review and accept the clinician prescription as the required documentation.
- Alternatively, require an electronic template, like the one developed for supplemental oxygen, for the prescribing clinician to complete with the necessary subjective elements with clinician attestation that along with the prescription would be the sole documentation to establish medical need and be sufficient for medical necessity review

VII. CONCLUSIONS

Current coverage policies that determine access to ventilators, bilevel devices, and CPAP devices are outdated and not supported by the clinical literature. In fact, a converse set of incentives exist that provide easier access to complex, more expensive devices primarily designed to provide ongoing life support to address respiratory failure. When it is significantly easier for clinicians to prescribe a device more expensive than a clinically appropriate device because of flawed policies that make the more appropriate device more difficult to prescribe, incentives become convoluted.

The recommendations included in this reconsideration request reflect a thorough review of the clinical literature by nationally recognized experts identified by the four major pulmonary/sleep societies in the United States. We believe that adoption of these recommendations will eliminate current barriers to appropriate device selection and reduce aggregate Medicare expenses as convoluted incentives that have increased program costs are eliminated.

Our societies look forward to the review of this request by CMS.

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