

Noninvasive Positive Pressure Ventilation in the Home for Chronic Respiratory Failure Consequent to Chronic Obstructive Pulmonary Disease

Comments of the American Thoracic Society

The American Thoracic Society is a medical professional society of over 16,000 physicians, nurses, respiratory therapists and allied health professionals dedicated to the prevention, detection, treatment and research of respiratory disease, critical care illness and sleep disordered breathing. The ATS publishes research and clinical practice guidelines the diagnosis and management of patients with respiratory diseases, including COPD.

ATS appreciates MEDCAC's consideration of this important issue. ATS is concerned that MEDCAC is taking too narrow an approach to coverage of ventilators and respiratory assist devices and encourages MEDCAC and CMS to think more broadly.

ATS will shortly publish an evidence-based clinical practice guideline that contains information that will be useful for the panel to consider. The ATS will shared a copy of the guideline with MEDCAC went it is published. While these MEDCAC comments cannot share the exact recommendations of the ATS guideline prior to its publication, it is fair to say that these the responses to the questions posed by MEDCAC are informed by the forthcoming clinical practice guideline.

Voting Questions:

For each voting question, please use the following scale identifying your level of confidence with a score of 1 being low or no confidence and 5 representing high confidence.

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

The types of NIPPV devices being referred to in the below questions are to be used in the home and are classified as:

- a. Home mechanical ventilator (HMV): A machine capable of delivering pressure targeted, volume targeted, and/or volume preset ventilation outside of the hospital setting. HMVs are usually the machine of choice for patients with tracheostomy, but may also be used in patients via a noninvasive interface. Compared to BPAP machines, HMVs typically have additional monitoring, ventilator control, safety, and backup power features.

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- b. Continuous positive airway pressure (CPAP): A machine that delivers a single level of positive airway pressure throughout the entire respiratory cycle (inspiration and expiration).
- c. Bi-level positive airway pressure (BPAP): A device that delivers two levels of positive airway pressure. On inspiration, the machine delivers an inspiratory positive airway pressure (IPAP). On expiration, the machine delivers an expiratory positive airway pressure (EPAP).

All questions below pertain to Medicare beneficiaries with CRF consequent to COPD.

1. *How confident are you that the evidence is sufficient to determine the **patient selection criteria** that will improve health outcomes (e.g. laboratory values, co-morbidities, frequency of exacerbations requiring ER or hospital admission, hospital discharge timing, pulmonary function tests, etc.) when used with any category of home NIPPV device?*

4

Discussion: If intermediate confidence (≥ 2.5) is present in Q1, please provide the selection criteria for the specific category of equipment.

Confident that patients with COPD who do not have stable hypercapnic respiratory failure are unlikely to benefit from BPAP or HMV. Those with COPD and stable hypercapnic respiratory failure are likely to benefit from BPAP with a backup rate, or, rarely, HMV.

Patients with COPD and obstructive sleep apnea (OSA) without hypercapnia are likely to benefit from CPAP.

2. *How confident are you that the evidence is sufficient to determine the **NIPPV equipment parameters** necessary to promote successful patient-related outcomes (e.g. decreased mortality, decreased frequency of exacerbations requiring ER or hospital admission, increased time to hospital re-admission for respiratory related disease, and improved physical function and quality of life)?*

3

For those with COPD and OSA, but not stable hypercapnia, CPAP set according to standard titration can improve patient related outcomes (PROs). Use of CPAP for COPD and OSA, without stable hypercapnia, is correlated with reduced mortality, reduction in ER and hospital admission, and quality of life.

For those with COPD and hypercapnia, BPAP with a back up rate will be needed, and adjusted to patient carbon dioxide level over time. Use of BPAP with a backup rate for those with COPD and stable hypercapnic respiratory failure is associated with reduced mortality, reduction in ER visits and improved quality of life.

Discussion: Are there any outcome measures that should be considered other than those noted above?

While not an outcome measure, the use of CO2 levels to determine adequate ventilation should be studied to help optimize settings and PROs.

Discussion: If intermediate confidence (≥ 2.5) is present in Q2, please provide the equipment parameters for the specific category of equipment.

3. How confident are you that any improved patient-related outcomes noted above made with any type of NIPPV device in the home, **can be attributed to the use of the equipment alone** as opposed to the concomitant provision of other support services like home respiratory therapists, home medication reconciliation and repeated elective hospital admissions?

Discussion: If intermediate confidence (≥ 2.5) of improved patient-related outcomes are present in Q3 for any type of home NIPPV device, please state that outcome and the associated category of equipment.

4

Use of CPAP for COPD and OSA, without stable hypercapnia is correlated with reduced mortality, reduction in ER and hospital admission, and quality of life. These outcomes are often without any home RTs, or other services.

Use of BPAP with a backup rate for those with COPD and stable hypercapnic respiratory failure is associated with reduced mortality, reduction in ER visits and improved quality of life. Some of the benefit may involve ancillary services, however, newer models of home initiation suggest hospitalization is not necessary. Additionally, substantial changes in PaCO₂ are unlikely to occur without BPAP. Some of the data come from randomized controlled trials in which the only difference is application of equipment.

4. How confident are you that the evidence is sufficient to provide the **patient usage parameters** that are necessary to achieve the successful patient outcomes in Q2?

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For those with COPD and OSA, there is no single value at which benefits begin. While most studies have used Medicare criteria (4 hours/night, on >70% of nights) there is no strong physiological rationale for a single cutoff. Rather, more use has been associated with more benefit. For those with stable hypercapnic COPD requiring BPAP more use is likely associated with greater benefit.

Discussion: If intermediate confidence (≥ 2.5) is present in Q4, please provide the patient usage criteria for the specific category of equipment.

General Comments:

1. Many studies with BPAP in COPD use BPAP with a back up rate. However, it is often difficult to get coverage for BPAP with a back up rate, so that many appropriate patients may end up with inadequate therapy.
2. Similarly, CMS requires patients to received blood gas testing, overnight oximetry and testing for OSA before they can receive NPPV. The ATS believes these requirements are excessive and would recommend that patients with spirometry-confirmed diagnosis of

COPD and documentation of stable hypercapnic (serum test) should be sufficient documentation for NPPV use.

3. Respiratory Therapists Care

The ATS notes with concern CMS's failure to recognize, measure and pay for the valuable therapeutic services that respiratory therapists provide in in-home settings. We urge CMS to recognize, measure and pay for the value services that RTs provide. Patients requiring true HMV are likely need additional services if they are expected to benefit.

4. There are few therapies that are associated with improved mortality in COPD – NIV may be one of the few.

We hope these comments are useful, The ATS looks forward to participation in the MEDCAC meeting on July 22, 2020.

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