June 22, 2020

Tara Hall
MEDCAC Coordinator
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee—July 22, 2020 (CMS-3395-N)
Submitted electronically via MedCACpresentations@cms.hhs.gov

Dear Ms. Hall:

The undersigned patient advocacy and provider organizations write to provide the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) our perspective on the impact of current coverage policies on patient access and the importance of the patient-physician relationship in making clinical and quality of life decisions regarding treatment with home mechanical ventilators (HMVs), bi-level positive airway pressure (BPAP) devices and continuous positive airway pressure (CPAP) devices.

We ask that the Centers for Medicare and Medicaid Services (CMS) refrain from revising coverage policies that determine access to respiratory devices based on MEDCAC's review of clinical evidence for a narrow patient population; namely, patients with chronic respiratory failure consequent to Chronic Obstructive Pulmonary Disease (COPD). Medicare policy currently also covers ventilators for the treatment of neuromuscular diseases and thoracic restrictive disorders, and we believe that the clinical relationship between ventilators and bi-level devices or RADs are strongly inter-related and that any comprehensive policy addressing home mechanical ventilation must also address these corollary devices and disease states.

Collectively, we represent diverse patient populations all with different types of respiratory care needs. We value the innovations in respiratory care that have improved health and quality of life for patients, and we trust physicians to evaluate innovations in respiratory care and make clinical decisions based on the unique circumstances of each individual patient in their care.

We have previously recommended convening a technical expert panel (TEP) to provide recommendations to CMS to update the National Coverage Determination (NCD) for home non-invasive ventilator (NIV) and respiratory assist device (RAD) coverage. The patient community urges CMS to reevaluate Medicare coverage policies that result in pushing patients inappropriately to certain respiratory devices. A TEP should make recommendations to CMS for revising the coverage policies, including defining "respiratory failure" for appropriate use criteria, establishing medically necessary criteria, and other issues to ensure access to medically appropriate devices in a timely manner. Members of Congress underscored the importance of mandating such an effort by introducing the Safeguarding Medicare Access to Respiratory Therapy (SMART) Act of 2019, a bill with bipartisan support of nearly 60 Members of Congress.

As patient and provider representatives, we are disappointed that the Agency has instead convened MEDCAC to evaluate clinical evidence for a limited patient population when patients with neuromuscular disease and thoracic restrictive disorders are equally important.

We urge you to refrain from restricting Medicare beneficiaries' access to respiratory care devices that their physicians determine are clinically appropriate and expand the evidence and patient population to address policies that are long overdue for reform.

Sincerely,

Alpha 1 Foundation
ALS Association
American Association for Respiratory Care
American Lung Association
American Thoracic Society
CHEST/American College of Physicians
COPD Foundation
CURE SMA
Dorney-Koppel Foundation
Les Turner ALS Foundation
Pulmonary Fibrosis Foundation
Respiratory Compromise Institute (RCI)
Respiratory Health Association
The LAM Foundation
U.S. COPD Coalition