



October 5, 2021

Meena Seshamani, M.D., Ph.D.

Deputy Administrator and Director of the Center for Medicare

Centers for Medicare & Medicaid Services

Room 301H-01

200 Independence Avenue S.W.

Washington, D.C. 20201

RE: Elimination of Medicare Reimbursement Disparities for Multi-function Ventilators Used in the Home

Dear Dr. Seshamani:

On behalf of the undersigned organizations, we are writing to express our strong support for the Centers for Medicare & Medicaid Services' ("CMS's") elimination of certain reimbursement

disparities between traditional ventilators and new generation multi-function ventilators. Specifically, we are urging CMS to revise its current policies so that payment for medically necessary accessories/supplies for home respiratory therapy is the same regardless of whether the beneficiary uses a traditional or multi-function ventilator. In this way, vulnerable ventilator-dependent Medicare beneficiaries may access the respiratory devices most suitable for their specific conditions.

The undersigned organizations are comprised of patient advocates and clinicians who are dedicated to the betterment of individuals with serious illness, as well as entities delivering critical healthcare interventions to these individuals in their homes. Collectively, our organizations are committed to improving the lives of individuals who depend on critical home respiratory therapy to treat their conditions, to stay out of the hospital, and to maintain a high quality of life.

Multi-function ventilators integrate several devices—ventilator, oxygen concentrator, cough assist, suction, and nebulizer—into a single piece of equipment. These ventilators provide invasive and non-invasive ventilation for vulnerable ventilator-dependent individuals requiring one or more respiratory therapies in addition to ventilation, including those individuals with amyotrophic lateral sclerosis (“ALS”), muscular dystrophy, spinal cord injuries, impaired lung function, bronchopulmonary dysplasia and other adult and pediatric lung conditions. Ventilator-dependent individuals often require more respiratory assistance to maintain their respiratory health as their conditions progress. Because some of these ventilator-dependent individuals benefit significantly from the use of a single integrated device rather than multiple, standalone pieces of equipment, we are urging equitable Medicare reimbursement policies for the individuals we represent and serve.

Historically, CMS has provided coverage for multiple separate devices—*i.e.*, multiple items of durable medical equipment, each delivering a separate function—when a beneficiary requires high levels of respiratory care. Except for standalone ventilators used in the home (HCPCS codes E0465 and E0466 for invasive and non-invasive ventilators, respectively) and oxygen equipment, medically necessary accessories/supplies related to respiratory equipment, such as cough assist devices, suction devices, and nebulizers, used in the home, generally are separately coded and reimbursed. Payment for each of these accessories/supplies are based on fee schedule amounts, which commonly are set nationally (except for items and accessories/supplies selected for competitive bidding). Depending on an individual’s medical needs, the accessories/supplies may be costly.

For multi-function ventilators (HCPCS code E0467), no separate payment is made for the medically necessary accessories/supplies for which separate payment is otherwise made when the same respiratory functions are furnished as standalone capped rental items. Yet, the regulatory formula for the national fee schedule amount for HCPCS code E0467 does not incorporate the aggregate additional cost of the accessories/supplies used with these additional respiratory functions. Suppliers faced with disparate Medicare pricing policies are compelled to

furnish only standalone ventilators along with the additional respiratory functions as standalone devices because the supplier may receive separate Medicare payment for the accessories/supplies used with the standalone respiratory equipment (e.g., masks, tubing, suction catheters, etc.). This results in access barriers. Notably, the access issue is validated by 2020 utilization data for home ventilators, showing that two years after the introduction of multi-function ventilators, less than one percent of Medicare beneficiaries using a ventilator have received this newer technology.

We have seen first-hand how multi-function ventilators offer some of our ventilator-assisted constituents and their caregivers an alternative that empowers them with increased mobility, ease of operation, uninterrupted ventilation between therapies, and safety features that boost independence and quality of life. The selection of the respiratory equipment for an individual's condition therefore should be based on their unique circumstances, including their home environment.

In sum, we strongly support eliminating disparate pricing policies that introduce bias against new technology and prevent beneficiaries from accessing the ventilator most appropriate for their conditions. Doing away with detrimental barriers would unquestionably open doors for vulnerable ventilator-dependent beneficiaries to the many potential benefits of treatment in the home through integration: improved infection control, remote utilization monitoring capabilities, greater patient engagement and enhanced quality of life.

We greatly appreciate your time and consideration of this request. Please do not hesitate to contact us with any questions or if you need any additional information.

Respectfully submitted,

ALS Hope Foundation

Augie's Quest to Cure ALS

Brigance Brigade Foundation

Compassionate Care ALS

EVERY90MINUTES

I AM ALS

Muscular Dystrophy Association

Post-Polio Health International including International Ventilator Users Network

Project ALS

Team Gleason

CC: CMS Administrator Chiquita Brooks-LaSure