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June 22, 2020

Ms. Tara Hall, Coordinator
Medicare Evidence Development and
Coverage Advisory Committee
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
Mail Stop: S3-02-01
7500 Security Boulevard
Baltimore, MD 21244

Re: MEDCAC on Noninvasive Positive Pressure Ventilation in Patients with Chronic Respiratory Failure Consequent to Chronic Obstructive Pulmonary Disease

Dear Ms. Hall:

The Advanced Medical Technology Association (AdvaMed) is pleased to submit the following comments in response to the Centers for Medicare & Medicaid Services' notice of the above-referenced Medicare Evidence Development Coverage Advisory Committee (MEDCAC) virtual meeting on July 22, 2020.

The Advanced Medical Technology Association (AdvaMed) is a trade association that leads efforts to advance medical technology in the United States and around the world. AdvaMed's member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies.

AdvaMed has concerns regarding both the substance and process of the upcoming MEDCAC meeting on noninvasive positive pressure ventilation (or NIV).

First, the coverage discussion should take into consideration the full scope of current clinical evidence available as well as the broad range of patient populations that could be affected by Medicare's coverage decisions. Focusing on patients with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD) limits discussion of broader ventilation policies (e.g., home mechanical ventilation, bi-level devices, respiratory assist devices) that address treatments for patients with other conditions, such as neuromuscular diseases and thoracic restrictive diseases. The discussion should cover this broader spectrum of devices and clinical indications, in order to ensure development of appropriate coverage policy. There has been significant innovation in ventilation that deserves proper

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examination, not only of the devices themselves, but the supportive services, care management, and digital technologies that accompany them.

Second, AdvaMed has expressed concerns in the past regarding the extremely limited timeframes CMS has provided for submitting comments in advance of a MEDCAC meeting. In this case, the meeting was announced on June 11, with comments due on June 22. This short period is just not reasonable to allow for the interested parties, including clinicians and other stakeholders, to respond in a meaningful way. The questions posed to the MEDCAC committee members are also difficult to respond to meaningfully.

The short comment period is particularly problematic in the midst of a novel coronavirus pandemic, which has created professional hardships for many that are further challenged by such an abbreviated response period.

Further, NIVs have figured prominently in the treatment of patients with COVID-19. This circumstance apparently was a factor in CMS's recent decision to remove these devices from the next round of the Medicare DMEPOS Competitive Bidding Program. Consequently, manufacturers have worked aggressively to increase capacity at the government's urging, compounding the difficulty of responding in such short order to this comment request.

AdvaMed has often commented to CMS that opportunities for stakeholders to engage early in the process and to participate in the development of the questions to be considered could help frame the discussion for the MEDCAC panel. Such collaboration in advance of a MEDCAC meeting would allow for a fuller discussion of all issues concerning the state of the evidence, current developments in technology and more.

We urge CMS to postpone the NIV MEDCAC to a later time, with changes that would address the broad scope of NIV issues. If CMS does not postpone the MEDCAC, we ask that the Agency provide additional time to allow stakeholders to provide the type of information that will move the discussion forward. **The short timeframe for developing the type of comments that will contribute in a meaningful way to the dialogue is particularly difficult at this time, during a global pandemic that acutely impacts clinicians on the front lines such as pulmonologists that are overwhelmed with clinical care.**

AdvaMed appreciates the opportunity to submit these comments and we urge CMS to consider these concerns. If you have questions or need additional information, please contact Chandra Branham, JD, AdvaMed Vice President, Payment & Health Care Delivery Policy, at cbranham@advamed.org.

Sincerely,



Don May
Executive Vice President
Payment & Health Care Delivery Policy