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Re: Philips voluntary medical device recall

Dear DME MAC Directors:

The undersigned medical societies and patient advocacy organizations wanted to alert the agency to a voluntary recall announced by Philips on June 14, 2021 for certain Philips Respironics devices used to treat obstructive sleep apnea (OSA), including continuous positive airway pressure (CPAP), bi-level positive airway pressure (BPAP) devices, and mechanical ventilators. The devices are being recalled due to two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips continuous and non-continuous ventilators: 1) PE-PUR foam may degrade into particles that may enter the device's air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The recall announcement advises that patients using recalled BPAP and CPAP devices should discontinue use of these devices and discuss the most appropriate options for continued treatment with their physicians. Patients are also advised to register on the Philips website to receive permanent corrective action for their devices. At this time, it is unclear how long it will take for Philips to process claims of recalled machines and provide replacement devices or parts.

The recalled positive airway pressure (PAP) devices are subject to the CMS Local Coverage Determination (LCD) Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718), which has specific requirements for continued coverage of a PAP device beyond the

first three months of therapy. This requirement states that "no sooner than the 31st day but no later than the 91st day after starting therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy." Our society members are concerned that the Philips Respironics recall will disrupt treatment for patients with OSA, and many will not meet the CMS adherence requirements before their device can be fixed or replaced. **Given that many patients will be affected by the recall, we are requesting support from CMS and private payers to temporarily suspend the 90-day adherence rule, to allow patients to have existing equipment repaired or receive new equipment from DME suppliers**. Although Philips has not provided estimates of how many patients and products are affected by this recall, we anticipate significant delays in equipment repairs and replacements and want to ensure that patients, who are no longer able to use their device due to the recall, are not penalized or required to have a new sleep test performed.

Additionally, L33718 includes requirements for replacing PAP equipment. The LCD states, "If a PAP device is replaced during the 5-year reasonable useful lifetime (RUL) because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation, sleep test, or trial period." **Although these devices have not been lost, stolen, or damaged due to a specific incident, the American Academy of Sleep Medicine (AASM), American Academy of Neurology (AAN), American College of Chest Physicians (CHEST), American Thoracic Society (ATS), Alliance of Sleep Apnea Partners (ASAP), and the American Sleep Apnea Association (ASAA) urge CMS to allow for an exception to the RUL requirements for the equipment repairs or replacements that will result from the Philips recall.** Our societies believe that it is both reasonable and necessary to allow DME suppliers to repair or replace the recalled equipment without requiring documentation of a new clinical evaluation, sleep test or trial period, and do not think patients should be responsible for the repair or replacement costs.

Our societies are working to provide the most up-to-date information and guidance to providers and patients about how to handle this recall. In the meantime, we encourage the agency to adopt these recommendations in response to the product recall. Please feel free to contact Diedra Gray, AASM Director of Health Policy, at dgray@aasm.org or 630-737-9700, for additional information or clarifications.

Sincerely,

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