



June 22, 2021

Re: Philips voluntary medical device recall

Dear Payer Representative:

The undersigned medical societies and patient advocacy organizations wanted to alert you 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.

Our society members are concerned that the Philips Respironics recall will disrupt treatment for patients with OSA, and many will not meet the adherence requirements set within payer coverage policies before their device can be fixed or replaced. **Given that many patients will be affected by the recall, we are requesting support from private payers to temporarily suspend any time-specified adherence rules, 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, **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 payers to allow for an exception to coverage requirements for only replacing PAP equipment after**

a certain number of years to account 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 you 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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