American Academy of Sleep Medicine

July 8, 2014

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-6050-P
PO Box 8013
Baltimore, MD 21244-8013

RE: Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items

On behalf of the American Academy of Sleep Medicine (AASM) I am writing to urge CMS not to implement a prior authorization process for continuous positive airway pressure (CPAP) therapy or respiratory assist devices (RADs).

The AASM represents over 8,500 member physicians and 2,500 accredited sleep centers. Our members work closely with DME suppliers to coordinate the provision and set-up of therapy for the treatment of obstructive sleep apnea (OSA). The proposed prior authorization process threatens to limit our members' ability to ensure their patients receive treatment in a timely manner. Coupled with the challenges of the Competitive Bidding Program, a prior authorization process creates significant hurdles for the Medicare patient seeking OSA therapy.

A time consuming prior authorization process sends the wrong message to OSA patients. The proposed rule suggests a typical prior authorization review process time of 10 days and an alternative expedited process that could take 2 days. The rule notes that the expedited process will be limited to items for which "applying the standard timeframe for making a decision could seriously jeopardize the life or health of the beneficiary." The AASM is concerned that patients made to wait for their CPAP or RAD therapy will have the misconception that their therapy is not mandatory for immediate or long term health. Untreated OSA is associated with several co-morbidities, including myocardial infarction, stroke, hypertension and diabetes. The proposed delays to DME delivery will impede our members' ability to educate patients about the severity of their illness.

The AASM is also concerned that the burdens of prior authorization will discourage qualified DME suppliers from working with Medicare patients. A specific prior authorization process was not outlined in the proposed rule. Rather, the rule indicates that prior authorization requirements will be based on national and local coverage requirements. The local coverage determinations for CPAP and RAD therapies are extensive. Preparing and submitting this information to CMS for every Medicare patient will be time consuming and labor intensive for DME suppliers. Coupled with the decreased reimbursement rates resulting from Competitive Bidding, a prior authorization process will make providing DME to Medicare patients impossible for the average DME company. A few national, mail order suppliers may be able to continue to meet the demands of prior

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authorization at lowered reimbursement rates, but the average local DME supplier will likely be forced to turn away Medicare patients. This will result in a lower standard of care for the patients who need one-on-one attention the most.

The AASM recognizes that fraud and claims error rates in the DME program are exceedingly high. We therefore understand that CMS is under pressure to find a solution to limit the number of inappropriately paid claims. However, because of the threat it poses to Medicare patients, we do not believe that adding administrative burdens, such as prior authorization for CPAP and RAD, is the appropriate solution. The DME LCD for PAP Devices for the Treatment of OSA includes safeguards against fraud. The clinical benefit of the PAP device must be documented in the patient record in order to obtain continued coverage for the device beyond the initial three months of therapy. Documentation of clinical benefit must include both a face-to-face clinical re-evaluation by the treating physician and objective evidence of adherence to use of the PAP device. Documentation of benefit should be sufficient evidence that the device has not been provided fraudulently.

In place of added administrative burdens, the AASM urges CMS to consider other possible solutions to improper DME payments. In the past, the AASM has approached CMS about an exception to the Stark Law, which would allow our member physicians to provide DME to their sleep patients. We continue to believe that putting DME in the hands of the qualified physician is the best way to limit fraud and abuse in the DME system.

Thank you for your consideration of our comments. If you have any questions about the negative impact prior authorization of CPAP and RAD will have on the Medicare population, please contact our Executive Director, Jerome A. Barrett (phone: 630-737-9700).

Sincerely,

Timothy Morgenthaler, MD
President

cc: Jerome A. Barrett