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March 23, 2023

E. Paul Amundson, MD FAAFP
CVS Caremark
Medical Director
One CVS Drive
Woonsocket, RI 02895
Sent via email: eamundson@cvshealth.com

Dear Dr. Amundson,

I am contacting you on behalf of the Payer Policy Review Committee of the American Academy of Sleep Medicine (AASM), a membership organization representing over 10,000 individual physician members and 2,500 AASM-accredited sleep centers. As the leading membership organization for sleep medicine, the AASM sets clinical standards for sleep medicine care by publishing new and updated evidence-based clinical practice guidelines. The Payer Policy Review Committee (PPRC) is comprised of physicians who are experts in the field of sleep medicine and well-versed in AASM guidelines and relevant literature. This committee is charged with communicating recommendations in the AASM guidelines to insurers and to assess alignment of insurers' policies to these guidelines.

The PPRC is reaching out in response to the recent changes made to the CVS Caremark prior authorization process for XYWAV® (calcium, magnesium, potassium, and sodium oxybates) oral solution, as the policy now requires a baseline history of 14 cataplexy attacks in a typical two-week period for coverage of narcolepsy treatment. Cataplexy refers to the total or partial loss of muscle tone, which can leave patients feeling paralyzed and/or experiencing hallucinations, in response to sudden emotion. Cataplexy also occurs very sporadically within narcolepsy patients. While prevalence data for narcolepsy patients with cataplexy is scarce, a Longstreth et al review of multinational published studies found a range of prevalence of narcolepsy with cataplexy to be between 25 and 50 per 100,000 persons¹.

Per the third edition of the International Classification of Sleep Disorders (ICSD-3), **there is no minimum number of cataplexy attacks required to meet the diagnostic criteria for narcolepsy.** The ICSD-3 includes the following diagnostic criteria for Narcolepsy type 1 (narcolepsy with cataplexy), where criteria A and B both must be met to meet the definition:

- A. The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months
- B. The presence of one or both of the following:
 - 1. Cataplexy and a mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.
 - 2. CSF hypocretin-1 concentrations, measure by immunoreactivity, is either ≤ 110 pg/mL or $< 1/3$ of mean values obtained in normal subjects with the same standardized assay.

The AASM recommends an update to the Criteria for Initial Approval for Cataplexy with Narcolepsy, to remove the minimum number of cataplexy attacks, as it is inconsistent with the AASM diagnostic criteria guidance and can cause delays and denials in treatment for patients with Narcolepsy Type 1. We, instead, encourage modification of the policy to align with the ICSD-3 diagnostic criteria. Thank you for your attention to this matter. If you have any questions about this issue or require any additional information, please contact AASM Director of Health Policy, Diedra Gray, at (630) 737-9700 or dgray@aasm.org.

Sincerely,

Kunwar P Vohra, MD, MBA, FAASM
Chair, AASM Payer Policy Review Committee

ⁱ Silber MH, Krahn LE, Olson EJ, Pankratz VS. The epidemiology of narcolepsy in Olmsted County, Minnesota: a population-based study. *Sleep*. 2002;25(2):197–202.