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Update to the AASM Clinical Practice Guideline: "The Treatment of Restless Legs Syndrome and Periodic Limb Movement Disorder in Adults—An Update for 2012: Practice Parameters with an Evidence-Based Systematic Review and Meta-Analyses"

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In January 2012, the AASM Board of Directors approved the Standards of Practice paper titled "The Treatment of Restless Legs Syndrome and Periodic Limb Movement Disorder in Adults - An Update for 2012: Practice Parameters with an Evidence-Based Systematic Review and Meta-Analyses." The 2012 update included a new drug not reviewed in the previous 2004 AASM guidelines for the treatment of Restless Legs Syndrome (RLS) and Periodic Limb Movement Disorder (PLMD) – rotigotine. Rotigotine was originally approved by the US Food and Drug Administration (FDA) for the treatment of signs and symptoms associated with early stage idiopathic Parkinson's disease. Additionally, rotigotine had been shown in clinical trials to be effective for the treatment of moderate-to-severe RLS. In 2008, rotigotine was withdrawn from the US market due to concerns about inconsistent absorption from the patch; therefore, rotigotine was not an FDA-approved treatment option for RLS or PLMD when the 2012 update was accepted for publication. Thus, despite high level evidence supporting the efficacy of this drug for the treatment of moderate-to-severe RLS, the Standards of Practice Committee (SPC) made no recommendation regarding the use of rotigotine in the setting of RLS.

The issue of drug absorption was subsequently resolved by the manufacturer, and the new formulation of rotigotine received FDA approval in April 2012. Rotigotine is currently FDA approved both for the treatment of signs and symptoms associated with advanced stage idiopathic Parkinson's disease, as well as for moderate-to-severe primary RLS. The change in the FDA status of rotigotine occurred after finalization and approval of the 2012 update and, therefore, is not reflected in the published paper. The new FDA status of rotigotine necessitated a change in the published recommendation level for the use of this medication in the treatment of RLS. Accordingly, the SPC has revised the recommendation level from "NO RECOMMENDATION" to a "GUIDELINE" level of recommendation. This new recommendation level reflects the high level of evidence for rotigotine coupled with uncertainty in the benefits/harms ratio due to limited clinical experience with this medication.

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