New Drug Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
November 29, 2018	
Amifampridine	FDA approved amifampridine tablets for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults. LEMS is a rare autoimmune disorder that affects the connection between nerves and muscles and causes weakness and other symptoms in affected patients. This is the first FDA approval of a treatment for LEMS. Efficacy of amifampridine was studied in two clinical trials that together included 64 adult patients who received amifampridine or placebo. The studies measured the Quantitative Myasthenia Gravis score (a 13-item physician-rated categorical scale assessing muscle weakness) and the Subject Global Impression (a 7-point scale on which patients rated their overall impression of the effects of the study treatment on their physical well-being). For both measures, the patients receiving amifampridine experienced a greater benefit than those on placebo. The most common adverse effects in the clinical trials were burning or prickling sensation, upper respiratory tract infection, abdominal pain, nausea, diarrhea, headache, elevated liver enzymes, back pain, hypertension, and muscle spasms. Seizures have been observed in patients without a history of seizures. Patients should inform their health care provider immediately if they have signs of hypersensitivity reactions, such as rash, hives, itching, fever, swelling, or trouble breathing.
(Firdapse—Catalyst Pharmaceuticals)	
FDA approves first treatment for Lambert-Eaton myasthenic syndrome	

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therapy must be based on the independent judgment of the clinician.