New Drug Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
October 1, 2018	
Galcanezumab-gnlm ***(Emgality—Eli Lilly)*** **New drug approved for preventive treatment of migraine in adults**	FDA has approved galcanezumab-gnlm, a calcitonin gene-related peptide (CGRP) antagonist, as a once-monthly, self-administered, S.C. 120-mg injection for preventive treatment of migraine in adults. Efficacy and safety of galcanezumab-gnlm were demonstrated in two Phase III clinical trials (EVOLVE-1 and EVOLVE-2) in patients with episodic migraine and one Phase III clinical trial (REGAIN) in patients with chronic migraine. Safety was evaluated in three clinical trials that included more than 2,500 patients. Hypersensitivity reactions (e.g., rash, urticaria and dyspnea) have been reported in clinical studies, can occur days after administration, and may be prolonged. The most common adverse effects were injection-site reactions. The recommended dose for galcanezumab-gnlm is 240 mg (two consecutive S.C. injections of 120 mg each), once as a loading dose, followed by monthly doses of 120 mg injected subcutaneously. Galcanezumab-gnlm is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients. Patients with commercial insurance are candidates to receive galcanezumab-gnlm for up to 12 months free as part of Lilly's patient support program.

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