

## New Indication for Migraine Drug

On June 4, 2019, the U.S. Food and Drug Administration (FDA) approved Emgality<sup>®</sup> (galcanezumab-gnlm) for the treatment of episodic cluster headache in adults. Emgality is an injectable solution from the new class of migraine agents known as calcitonin gene-related peptide (CGRP) antagonists. It is the first treatment available that reduces the frequency of episodic cluster headache attacks.

Cluster headaches are severe and debilitating headaches that cause patients extreme pain. This type of headache often occurs in clusters, or periods, of several weeks or months at a time, and the episodes seem to appear at the same time each day. Cluster headache attacks usually last from minutes to a few hours and symptoms include drooping eyelids, runny nose, watery eyes and facial sweating.

Emgality was previously approved only for the prevention of migraine headaches and is now approved for the treatment of cluster headaches. The dosing for cluster headache treatment is different than dosing when used for migraine headache prevention. As a result, the product is now available in the strength of 100 mg per milliliter (mL). For cluster headaches, patients receive 300 mg of galcanezumab at the onset of a cluster headache period, followed by once-monthly injections of 300 mg until the cluster period has subsided.

Galcanezumab is the first monoclonal antibody indicated for the treatment of cluster headaches and is supplied in prefilled syringes for self-injection. The new 100 mg/1 mL injection has an average wholesale price (AWP) of \$575.00 per prefilled syringe. The 300 mg dose for a cluster headache would require three 100 mg/1 mL syringes carrying a monthly AWP \$1,725.00.

For additional details on this new indication for Emgality, view the FDA's [press release](#) or visit the manufacturer's [website](#).

### References

1. FDA approves first treatment for episodic cluster headache that reduces the frequency of attacks. FDA News Release. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-episodic-cluster-headache-reduces-frequency-attacks>. Updated June 4, 2019. Accessed June 24, 2019.
2. Emgality [package insert]. Lakewood, NJ: Eli Lilly and Company; June 2019. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/761063s003lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761063s003lbl.pdf). Accessed June 24, 2019.

