# Clinical Update:

# New Class of Agents for Migraine Prevention

**In 2018, the U.S. Food and Drug Administration (FDA) approved three new preventative migraine therapies for use in adults. These agents are from a novel class of medications called the calcitonin gene-related peptide antagonists or CGRP antagonists. Additional medications from this new class of drugs are under development.**

All three new CGRP antagonists are indicated for the preventive treatment of migraine in adults. These agents include:

- **Aimovig®** (erenumab-aooe)
- **Ajovy®** (fremanezumab-vfrm)
- **Emgality®** (galcanezumab-gnlm)

These products are administered once a month by subcutaneous (SC) injection into the abdomen, thigh or upper arm. Ajovy also can be administered on a quarterly basis, and Emgality can also be administered via SC injection into the buttocks.

## CGRP Antagonists

These new therapies can be used in patients with episodic or chronic migraines.

- **Episodic migraine** – fewer than 15 migraine or headache days per month
- **Chronic migraine** – 15 or more headache days per month with at least 8 of these being migraine headache days

The novel therapies exert their effects by binding to either the calcitonin gene-related peptide (CGRP) or its receptor and blocking downstream functions. Data suggests this peptide is elevated in patients who experience migraines. Therefore, decreasing the effects of the peptide may improve migraine symptoms.

This new class of drugs is expected to compete with other FDA-approved medications for preventing migraines, such as, topiramate, propranolol and Depakote® (divalproex). Botox® (onabotulinumtoxinA) is also FDA-approved for migraine prevention in adults with chronic migraine.

## Product Comparison

| Brand Name | Supplied | Dosing | AWP per Month |
|---|---|---|---|
| **Aimovig** (erenumab-aooe) | 70 mg/mL solution in a single-dose autoinjector | 70 mg to 140 mg once monthly | $690.00 |
| **Ajovy** (fremanezumab-vfrm) | 225 mg/1.5 mL solution in a single-dose prefilled syringe | 225 mg monthly or 675 mg quarterly | $690.00 |
| **Emgality** (galcanezumab-gnlm) | 120 mg/mL solution in a single-dose prefilled autoinjector | 240 mg loading dose, followed by 120 mg monthly | $690.00 |

## More about Aimovig

Aimovig (erenumab-aooe) received FDA approval in May 2018 and was the first to market in this new class of drugs. It can be used in patients with either episodic or chronic migraines.

- Studies demonstrated a statistically significant reduction in the number of migraine days per month with erenumab compared to placebo. On average, patients on erenumab demonstrated 1 to 2.5 fewer monthly migraine days per month compared to placebo.
- The most common side effects experienced with this therapy were injection site reactions and constipation.

Erenumab is supplied as a 70 mg/mL solution in an auto-injector designed for patient or caregiver administration. The needle shield of the autoinjector contains a derivative of latex and has the potential to cause allergic reactions in susceptible individuals. It is dosed as 70 mg or 140 mg each month with the 140 mg dose being administered as two consecutive injections of 70 mg.

## More about Ajovy

Ajovy (fremanezumab-vfrm) received FDA approval in September 2018 and was the second CGRP antagonist to receive approval. It is also indicated for the preventive treatment of migraine in adults. It can be used in patients with either chronic or episodic migraines.

- Studies demonstrated a statistically significant reduction in the number of headache days per month with fremanezumab compared to placebo. Patients receiving fremanezumab demonstrated an average reduction of 1.5 migraine days per month compared to placebo.
- The most common side effects occurring in patients treated with Ajovy were injection site reactions. Ajovy carries warnings/precautions for allergic reactions and should not be used in patients who have experienced an allergic reaction to the product or any of its ingredients.

Fremanezumab is supplied as a 225 mg/1.5 mL solution in a prefilled syringe. It is dosed as 225 mg monthly or 675 mg every 3 months (quarterly). The 675 mg quarterly dosage is administered as three consecutive injections of 225 mg. A patient or caregiver can administer the product.

## More about Emgality

Emgality (galcanezumab-gnlm) received FDA approval in late September 2018. It is also indicated for the preventive treatment of migraine in adults and can be used in patients with episodic or chronic migraines.

- Studies demonstrated statistically significant reductions in the number of headache days per month with galcanezumab compared to placebo. Patients treated with galcanezumab had an average reduction of about 2 fewer headache days per month compared to placebo.

- The most common side effects reported in patients taking galcanezumab were injection site reactions. Similar to Ajovy, the product also carries a warning/precaution regarding the potential for allergic reactions. It should not be used in patients with a prior history of an allergic reaction to the product or any of its ingredients.

Galcanezumab is supplied as a 120 mg/mL solution in a prefilled autoinjector designed for patient or caregiver administration. It is dosed as a 240 mg loading dose followed by 120 mg monthly. The 240 mg loading dose is administered as two consecutive injections of 120 mg.

For additional details on these novel migraine prevention therapies, view the respective manufacturers' press releases: Aimovig, Ajovy and Emgality. CastiaRx plans to provide ongoing communication regarding new product approvals from this novel class of medications.

## References


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