



Severe Migraines: Should You Try the New CGRP Antibody Therapy?



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On May 17, 2018, the Food and Drug Administration approved a new preventive therapy for migraine, a serious condition that ranks as one of the leading causes of disability among healthy people.

The newly approved drug, erenumab (brand name Aimovig™), was designed to prevent migraine in those who experience frequent migraines, particularly those who experience chronic migraine (15 or more headache days per month), and who haven't benefited from, or cannot tolerate, existing treatments.

Erenumab prevents migraines by blocking a widely-distributed substance in the body, known as calcitonin gene-related peptide, or CGRP. Developed by Amgen® and Novartis, the medicine is a monthly injection that belongs to a class of drugs known [monoclonal antibodies](#), which are immune cells that have been engineered to target and block CGRP, or its receptor. Three other companies are currently awaiting FDA approval for similar CGRP monoclonal antibody therapies.



Migraines are a common chronic condition, estimated to affect about a billion people worldwide.

“ The newly approved drug, erenumab, was designed to prevent migraine in those who experience frequent migraines, particularly those who experience chronic migraine.”

Neurologist and migraine specialist [Elizabeth Loder, MD, MPH](#), Chief of the [Division of Headache and Pain](#) at Brigham and Women's Hospital Faulkner Hospital, has treated patients with migraines for over 30 years. Dr. Loder has closely followed the development of CGRP-blocking antibodies, and recently wrote an [editorial in the journal JAMA](#).

Dr. Loder is encouraged by the class of drugs that works by an entirely new mechanism, but calls CGRP-inhibiting drugs “progress, not a panacea,” noting that these drugs

haven't consistently met a common measure of success for migraine prevention, a 50 percent reduction in migraine attack or frequency or days in 50 percent of patients.

The pros and cons of CGRP monoclonal antibody therapy

There are currently no existing treatments that eliminate migraines. The only FDA-approved treatment for chronic migraine is onabotulinumtoxinA (brand name Botox®). Given as injections every three months, this therapy modestly reduces the frequency of headaches for some people.

Though not specifically approved for chronic migraine, there are other FDA-approved preventive treatments for migraine, including propranolol, topiramate, and sodium divalproex. Treatments such as lisinopril are not approved by the FDA, but are used "off label" to treat migraine.

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“These CGRP monoclonal antibodies offer some advantages to existing treatments for some patients. They are well-tolerated and showed fewer side effects in clinical trials when compared to existing treatments. They also offer a lower risk of drug interactions, which is an important consideration for people with other medical conditions. They are also injected on a regular schedule, which helps patients adhere to treatment,” said Dr. Loder.

In her *JAMA* editorial, Dr. Loder reviewed the efficacy and tolerability of injections of the preventative migraine treatment fremanezumab, which is currently being reviewed by the FDA, and noted that while fremanezumab was more effective than placebo in clinical trials, the drug provided only a modest reduction in migraines – subjects had 1.3 to 1.9 fewer days per month of migraine compared to placebo.

Who should try new antibody treatments for migraine?

In a recent commentary in *JAMA Neurology*, [“Who Should Try New Antibody Treatments for Migraine?”](#) Dr. Loder and her colleague [Rebecca Burch, MD](#), a headache medicine specialist, provided guidance for patients and providers who are considering the prevention of migraine with a CGRP monoclonal antibody therapy.

Strongly consider CGRP monoclonal antibody therapy

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chronic migraines and are severely disabled or haven’t benefited from existing treatments, we generally recommend trying CGRP monoclonal antibodies,” advises Dr. Loder.

In addition, you should consider this therapy if you:

- have difficulty tolerating existing alternative migraine treatments.
- have difficulty adhering to a medication regimen.
- take several medications and there is concern about drug interactions.

Avoid taking CGRP monoclonal antibody therapy

“If you experience infrequent migraines and respond well to medicines used to treat individuals then you probably do not need these therapies,” said Dr. Loder.

In addition, you should probably avoid these drugs if you:

- have cardiovascular disease, or are at high risk of heart disease.
- are pregnant or trying to become pregnant. These therapies have a long duration of action (over a month), which would be half of the first trimester of pregnancy.

“ The long-term safety risks of this class of medicines are still unknown. If you are tolerating existing treatments and are satisfied with your control of migraines, it’s probably not worth the unknown long-term risks.”

Exercise caution with CGRP monoclonal antibody therapy

“The long-term safety risks of this class of medicines are still unknown. If you are tolerating existing treatments and are satisfied with your control of migraines, it’s probably not worth the unknown long-term risks,” said Dr. Loder.

In addition, other considerations include:

- It may not be appropriate to generalize findings to patients with psychiatric or complex medical conditions, as such patients were excluded from clinical trials.
- Blocking the activity of CGRP may be risky in patients who are at high risk of cardiovascular disease or stroke.

Cautiously optimistic

“The treatment of migraine is a complex clinical challenge. A therapy that works extraordinarily well for one patient may provide little benefit or produce undesirable side effects in another patient,” said Dr. Loder.

She still remembers when triptan medications, such as Imitrex (sumatriptan), became available 20 years ago. At that time, the medical community was concerned about the potential long-term safety of these drugs.

“The triptans ultimately proved to be quite safe over the long-term. It might be the same with these new monoclonal antibody therapies, but we need to wait and see,” said Dr. Loder.

- Dustin G.

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