Drug Monograph

Drug/Drug Class:	**Aimovig™(erenumab-aooe) subcutaneous injection/ Headache/Migraine**
Prepared for:	MO HealthNet
Prepared by:	Conduent

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary (1)

Purpose:	The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, require a clinical edit or require prior authorization for use.
Dosage Forms & Manufacturer:	Aimovig™ is available in a single-dose prefilled syringe or single-dose prefilled SureClick® auto injector for subcutaneous injection in the abdomen, thigh, or upper arm. Manufactured for: Amgen Inc., Thousand Oaks, CA 91320
Summary of Findings:	The efficacy of Aimovig™ was evaluated as a preventive treatment of adult patients with a history of migraines in three randomized, double-blind, placebo-controlled studies. In Study 1, the primary efficacy endpoint was the reduction of monthly migraine days (MMD) from baseline. Patients receiving Aimovig™ 70 mg had a decrease of 3.2 MMD compared to a decrease of 3.7 MMD for patients receiving Aimovig™ 140 mg and a decrease of 1.8 MMD in patients receiving placebo. These results were statistically significant.
Status Recommendation:	☐ Prior Authorization (PA) Required ☐ Open Access ☒ Clinical Edit ☐ PDL
Type of PA Criteria:	☐ Increased Risk of ADE ☐ Preferred Agent ☒ Appropriate Indications ☐ No PA Required

Purpose

The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug, a clinical edit drug or an open access drug. While prescription expenditures are increasing at double-digit rates, payers are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

Introduction [2]

Migraine is a neurological disease affecting 39 million people in the US and 1 billion people worldwide. It is the third most prevalent illness in the world. Patients often describe migraine headache pain as an intense pulsing or throbbing pain in one area of the head. Additional symptoms include nausea and/or vomiting and sensitivity to light and sound. Patients with migraine tend to have recurring attacks triggered by a number of different factors including stress, hormonal changes, bright or flashing lights, lack of food or sleep and diet.

Migraine tends to run in families with about 90% of patients having a family history of migraine. While migraine affects women, men and children, there are three times as many adult women who suffer from migraine compared to adult men.

Dosage Form(s) [1]

Aimovig™ is available in a single-dose prefilled syringe or single-dose prefilled SureClick® auto injector for subcutaneous injection in the abdomen, thigh, or upper arm.

Manufacturer [1]

Manufactured for: Amgen Inc., Thousand Oaks, CA 91320

Indication(s) [1]

Aimovig™ is indicated for the preventive treatment of migraine in adults

Clinical Efficacy [1,3] (mechanism of action/pharmacology, comparative efficacy)

Aimovig™ (erenumab-aooe) is a human immunoglobulin G2 (IgG2) monoclonal antibody that binds to the calcitonin gene-related peptide (CGRP) and antagonizes CGRP receptor function. As a result of binding to the CGRP receptor, erenumab-aooe exhibits non-linear kinetics.

Pharmacodynamics/Kinetics:

	Aimovig™
Bioavailability	82%
Metabolism	Via a nonspecific, non-saturable proteolytic pathway
Time to peak	6 days
Half-life	28 days

Clinical Studies

STUDY DESIGN	Study 1 was a 6-month randomized, multi-center, placebo-controlled, double-blind study (N=955) evaluating Aimovig™ for the preventive treatment of episodic migraine. Study 2 was a 3-month, randomized, multi-center, placebo-controlled, double-blind study (N=667) evaluating Aimovig™ as a preventive treatment of chronic migraine.
INCLUSION CRITERIA	Adult patients with a history of episodic or chronic migraine
EXCLUSION CRITERIA	Patients with a history of medication overuse headache caused by opiate overuse, patients with concurrent use of migraine preventive treatments, patients with myocardial infarction, stroke, transient ischemic attacks, unstable angina coronary artery bypass surgery or other revascularization procedures within 12 months.
TREATMENT REGIMEN	Patients were randomized to receive Aimovig™ 70 mg once monthly, Aimovig™ 140 mg once monthly, or placebo. Patients were allowed to use acute headache treatments including migraine-specific medications and NSAIDs during the study.
RESULTS	In study 1, the primary efficacy endpoint was the change from baseline in monthly migraine days through treatment periods 4 to 6 for patients with episodic migraines. The decrease in MMD was 3.2 for patients receiving Aimovig™ 70 mg, 3.7 MMD for patients receiving Aimovig™ 140 mg, and 1.8 MMD for patients receiving placebo. The secondary endpoints included the achievement of a ≥ 50% reduction from baseline (≥ 50% MMD responders) in the mean MMD over months 4 to 6. 43.3% of patients receiving Aimovig™ 70 mg were considered responders, compared to 50% of patients receiving Aimovig™ 140 mg and 26.6% of patients receiving placebo. In study 3, the primary efficacy endpoint was the change from baseline in monthly migraine days at month 3 for patients with chronic migraines. Patients receiving Aimovig™ 70 mg and 140 mg had a decrease of 6.6 MMD, while patients receiving placebo had a decrease of 4.2 MMD.
SAFETY	The most common adverse effects (incidence of at least 3%) for the Aimovig™ groups were injection site reactions and constipation.

Contraindications [1]

- None

Warnings and Precautions [1]

- Latex: the needle cap of the Aimovig™ prefilled syringe contains dry natural rubber, which is a derivative of latex and may cause allergic reactions in people with latex sensitivity
- Patients should be adequately instructed on proper self-administration of this medication

Adverse Effects [1]

Most common, ≥ 2%	Aimovig™ 70 mg Once Monthly (N=787)	Aimovig™ 140 mg Once Monthly (N=507)	Placebo (N=890)
Injection site reactions	6%	5%	3%
Constipation	1%	3%	1%
Cramps, muscle spasms	<1%	2%	<1%

Drug Interactions [1,3]

- Belimumab: Monoclonal Antibodies may enhance the toxic effect of Belimumab
- Aimovig™ is not metabolized by CYP450 enzymes; therefore interactions with concomitant medications metabolized by CYP450s enzymes are unlikely.

Dosage and Administration [1]

The FDA recommended dose is 70 mg once monthly, with benefit in some patients of 140 mg once monthly. Aimovig should be administered subcutaneously in the abdomen, thigh, or upper arm.

Cost

GENERIC NAME	BRAND NAME	MANUFACTURER	DOSE	COST/ MONTH
Erenumab-aooe	Aimovig™	Amgen	70 mg/mL once monthly	$575*

* Wholesale Acquisition Cost

Conclusion

Aimovig™ is a fully human monoclonal antibody that selectively binds to the calcitonin gene-related peptide (CGRP). Aimovig™ is the first FDA-approved preventive migraine treatment in a new class of drugs that work by blocking the activity of CGRP. CGRP is involved in the

pathophysiological mechanisms underlying migraine through the nociceptive mechanisms in the trigeminovascular system. Aimovig™ is indicated for the prevention of migraine in adults with episodic or chronic migraine. Clinical results showed that patients taking Aimovig™ had a significant reduction in migraine days per month compared to placebo controls. Aimovig™ is the first drug recently developed specifically for migraine prevention.

Recommendation

The Division recommends adding this drug as a clinical edit.

References

1) Aimovig. Retrieved 07/19/2018 from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b998ed05-94b0-47fd-b28f-cddd1e128fd8
2) Migraine Research Foundation. Retrieved 07/19/2018 from: https://migraineresearchfoundation.org/about-migraine/migraine-facts/
3) Lexicomp. Retrieved 07/19/2018 from: https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/6647531

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