Aimovig™ (erenumab-aooe)

Policy # 00646
Original Effective Date: 11/21/2018
Current Effective Date: 11/21/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Aimovig™‡ (erenumab-aooe) to be **eligible for coverage**** when the patient selection criteria are met**.**

Patient Selection Criteria
Coverage eligibility for Aimovig (erenumab-aooe) will be considered when the following criteria are met:

- Aimovig will be used for the prevention of migraine headaches; AND
- Patient is 18 years of age or older; AND
- Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventive medication); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has tried and failed (e.g. intolerance or inadequate response) at least TWO standard prophylactic pharmacologic therapies, each from a different pharmacologic class unless there is clinical evidence or patient history that suggests the use of the required prophylactic pharmacologic therapies from different classes will be ineffective or cause an adverse reaction to the patient. [Note: prophylactic pharmacologic classes include anticonvulsants (e.g. topiramate, divalproex), beta blockers (e.g. propranolol, metoprolol, nadolol), tricyclic antidepressants (e.g. amitriptyline, nortriptyline), calcium channel blockers (e.g. verapamil), and botulinum toxins (e.g. Botox®‡).] AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has tried and failed (e.g. intolerance or inadequate response) at least one generic triptan therapy (e.g. sumatriptan) or the patient has a contraindication to the use of triptans.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of Aimovig (erenumab-aooe) when the patient has fewer than 4 migraine headache days per month, has not tried at least 2 prophylactic medications from different pharmacologic classes, or has not tried a triptan to be **not medically necessary.****

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When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Aimovig (erenumab-aooe) for conditions other than migraine headache prevention or for patients younger than 18 years of age to be **investigational.***

Background/Overview

Aimovig is a first-in-class human monoclonal antibody that is indicated to prevent migraine headache attacks in adults. It binds to the calcitonin gene-related peptide (CGRP) receptor and antagonizes CGRP receptor function. CGRP has potent vasodilating actions and is thought to be associated with many of the phenomenon occurring with migraine attack (e.g. aura, pain, photophobia, and nausea). The recommended dosage of Aimovig is 70 mg injected subcutaneously once monthly. Some patients may benefit from a dosage of 140 mg once monthly which is administered as two consecutive subcutaneous injections of 70 mg each. The safety profile of Aimovig is favorable with relatively few adverse events and no contraindications or warnings/precautions noted in the labeling.

Migraine is a common, chronic condition marked by paroxysmal, unilateral attacks of moderate to severe throbbing headache which is aggravated by routine physical activity and associated with nausea, vomiting, and/or photophobia and phonophopbia. Migraine headache episodes typically last 4 to 72 hours if untreated. Migraine affects approximately 13% of adults in the United States with three times more women affected than men. There are two major subtypes of migraine: migraine with aura and without aura. In up to 30% of patients, aura precedes migraine headache and is typically characterized by any combination of visual, hemisensory, or language abnormalities, with the most common being visual. Migraines have been defined as chronic or episodic. Chronic migraine is described by the International Headache Society as headache occurring on $\geq$15 days per month for more than 3 months, which has the features of migraine headache on $\geq$8 days per month. Episodic migraine is characterized by headaches that occur <15 days per month. Patients with episodic migraine may transform to chronic migraine over time at a rate of about 2.5% of patients per year. Potential strategies for preventing migraine transformation include preventing and treating headaches, lifestyle modifications, or effective management of comorbidities. Episodic migraine is more common than chronic migraine; however, chronic migraine is associated with a markedly greater personal and societal burden.

The American Academy of Neurology (AAN) published an evidence-based guideline update for the prevention of episodic migraine in 2012. These guidelines recommend divalproex sodium, sodium valproate, topiramate, metoprolol, propranolol, and timolol as effective for migraine prevention and suggest that they should be offered to patients with migraine to reduce migraine attack frequency and severity. The guidelines have not been updated to address Aimovig. Guidelines also support the use of angiotensin receptor blockers, angiotensin converting enzyme inhibitors, tricyclic antidepressants, and other antidepressants as preventative therapies. Botox is indicated only for the prophylaxis of chronic migraine in adults and is administered intramuscularly once every 12 weeks.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Aimovig was approved in May 2018 for the preventive treatment of migraine in adults.

Rationale/Source

Aimovig's efficacy was assessed in three randomized, double-blind, placebo-controlled studies: two studies in patients with episodic migraine (4 to 14 migraine days per month) and one study in patients with chronic migraine (≥15 headache days per month).

Study 1 was a randomized, multi-center, 6-month, placebo-controlled, double-blind study evaluating Aimovig for the preventive treatment of episodic migraine. A total of 955 patients were randomized to receive Aimovig 70 mg, Aimovig 140 mg, or placebo by subcutaneous injection once monthly for 6 months. Patients were allowed to use acute headache treatments including migraine-specific medications (i.e., triptans, ergotamine derivatives) and NSAIDs during the study. The primary efficacy endpoint was the change from baseline in mean monthly migraine days over months 4 to 6. Aimovig treatment demonstrated a statistically significant reduction in mean monthly migraine days at both doses. The 70 mg group had a mean monthly migraine day reduction of -3.2 days, the 140 mg group had a mean monthly migraine day reduction of -3.7 days, and the placebo group had a mean monthly migraine day reduction of -1.8 days.

Study 2 was a randomized, multi-center, 3-month, placebo-controlled, double-blind study evaluating Aimovig for the preventive treatment of episodic migraine. A total of 577 patients with a history of episodic migraine were randomized to receive either Aimovig 70 mg or placebo by subcutaneous injection once monthly for 3 months. Patients were allowed to use acute headache treatments including migraine-specific medications (i.e. triptans, ergotamine derivatives) and NSAIDs during the study. The primary efficacy endpoint was the change from baseline in monthly migraine days at month 3. Aimovig treatment demonstrated a statistically significant improvement in the primary endpoint compared to placebo. Patients in the Aimovig group had a mean monthly migraine day change from baseline of -2.9 days compared to the placebo group which had a change from baseline of -1.8 days.

Study 3 was a randomized, multi-center, 3-month, placebo-controlled, double-blind study evaluating Aimovig as a preventive treatment of chronic migraine. A total of 667 patients with a history of chronic migraine with or without aura were randomized to receive Aimovig 70 mg, Aimovig 140 mg, or placebo by subcutaneous injection once monthly for 3 months. Patients were allowed to use acute headache treatments including migraine-specific medications (i.e. triptans, ergotamine derivatives) and NSAIDs during the study. The primary efficacy endpoint was the change from baseline in monthly migraine days at month 3. Aimovig treatment demonstrated statistically significant improvement in the primary endpoint at both Aimovig doses compared to placebo. Patients in both the 70 mg group and the 140 mg group had a mean monthly migraine day change from baseline of -6.6 days compared to -4.2 days in the placebo group.

References

1. Aimovig [package insert]. Amgen. Thousand Oaks, CA. Updated May 2018.
2. Aimovig Drug Evaluation. Express Scripts. Updated May 2018.

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Policy History

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11/08/2018 Medical Policy Committee review
11/21/2018 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 11/2019

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.