Overview

Calcitonin gene-related peptide (CGRP) is a therapeutic target in migraine headaches because of its role in mediating trigeminovascular pain transmission and neurogenic inflammation. Ajovy® (fremanezumab-vfrm) is a human monoclonal antibody that binds to both isoforms of the CGRP ligand and is effective for prevention of episodic migraine.

Food and Drug Administration (FDA) Approved Indications:

- Ajovy® (fremanezumab-vfrm) is a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults.

Clinical Guideline Coverage Criteria

The Plan may cover Ajovy® (fremanezumab-vfrm) when all the following clinical criteria is met:

Initial Authorization Criteria:

1. The Member has a diagnosis of chronic migraine headaches.

AND

2. Ajovy (fremanezumab-vfrm) is being prescribed for the preventive treatment of migraine headaches

AND

3. The Member is 18 years of age or older
Reauthorization Criteria:
The Plan may cover Ajovy® (fremanezumab-vfrm) when all the following clinical criteria is met:

1. The Member has a diagnosis of chronic migraine headaches.
2. The Member has experienced a positive response to therapy as demonstrated by one (1) of the following:
   a. Documented reduction in headache frequency, severity, or duration
   b. Documented reduction in the use of acute migraine medications (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], triptans) since starting Ajovy® (fremanezumab-vfrm) therapy

Limitations

- Initial authorization is limited to 6 months if initial coverage criteria are met.
- Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J3031</td>
<td>Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)</td>
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References:


Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)
September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member’s health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a
guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.