

Your guide to preparing a Letter of Medical Necessity

A Letter of Medical Necessity is used when the insurance company denies a request to pay for a medication. It can be helpful to patients when the medication is:

- · Subject to step therapy or prior authorization
- · Not available in that payer's formulary
- In need of supplemental information that may be needed to ensure patient access to therapy

The letter should contain the information needed to support the proposition that the requested medication is necessary to meet the medical needs of your patient.

The following sample letter can be helpful for you, the healthcare provider (HCP), and your office staff when a Letter of Medical Necessity is needed. The content of the letter should include:

- The patient's diagnosis, condition, and medical history
- Information about your patient's previous therapies and his/her response to those therapies
- A summary of your opinion about the patient's prognosis without treatment and documentation that supports your position
- All necessary contact information

This guide and the following sample letter are presented for informational purposes only. They are not intended to provide reimbursement or legal advice. When in doubt, you are encouraged to contact third-party payers for specific information on their coverage policies. **Teva recommends confirming the information that is required to include in a Letter of Medical Necessity with individual payers.**

INDICATION

AJOVY® (fremanezumab-vfrm) injection is indicated for the preventive treatment of migraine in adults.

IMPORTANT SAFETY INFORMATION

Contraindications: AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients. Reactions have included anaphylaxis and angioedema.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration. Cases of anaphylaxis and angioedema have been reported in the postmarketing setting. If a hypersensitivity reaction occurs, consider discontinuing AJOVY and institute appropriate therapy.

Adverse Reactions: The most common adverse reactions in clinical trials (≥5% and greater than placebo) were injection site reactions.

Please see the full <u>Prescribing Information</u> for AJOVY.



[Date]

[Payer Name] RE: Coverage of AJOVY[®] (fremanezumab-vfrm) Injection [Payer Representative] [Payer Address] [City, State ZIP Code] [Payer Fax Number]

[Patient Name] [Policy Name] [Group Number] [Patient DOB] [Patient Age] [Patient Sex]

Attention: [Medical/Pharmacy Director], [Department]

Dear [Medical/Pharmacy Director],

I am writing to document the medical necessity of AJOVY, which I have prescribed for my patient, [Patient Name], [Policy Number].

AJOVY is a prescription medicine used for the preventive treatment of migraine in adults. The full Prescribing Information for AJOVY can be found at <u>www.AJOVY.com</u>.

[Patient Name]'s medical history and course of treatment are as follows:

Date of Birth

[MM/DD/YYYY]

Diagnosis

Episodic Migraine (4-14 headache days per month)

Chronic Migraine (15 or more headache days per month, of which 8 or more are migraine days)

Other diagnosis with ICD-10 Code: [Diagnosis and ICD-10 Code]

Migraine Frequency

 Currently the patient experiences, on average: [# of Days] migraine days per month [# of Months] months

Migraine History

• The patient has experienced an inadequate response to the following medications after a reasonable duration and adequate dose (list medications).

Medication Name(s)	Dose	Duration

The medication will not be used in combination with another anti-CGRP or anti-CGRP-R.

The patient's headaches have been evaluated for, and **are not** caused by, medication rebound or overutilization or lifestyle factors.

Additional information pertinent to this request:

In my clinical opinion, AJOVY[®] (fremanezumab-vfrm) injection is medically necessary and reasonable for [Patient Name]'s medical condition. Please contact me at [Office Phone Number] if any additional information is required to ensure the prompt approval of this course of treatment.

Sincerely,

[Your signature]

[Enclosures]

[List enclosures as appropriate. Examples of enclosures include: excerpt(s) from patient's medical record, Explanation of Benefits (EOB), relevant treatment guidelines, and product Prescribing Information.]