**Instructions for Use: Letter of Appeal for 300mg Dosage Template with Clinical Reference**

If your patient is denied coverage, you may explain your clinical rationale for prescribing VYEPTI® (eptinezumab-jjmr) through a Letter of Appeal. This sample letter will help demonstrate a patient’s need for access to therapy and provide examples of published clinical references, which may support the prior authorization submission for VYEPTI for your patient.

To use the template:

Replace all or delete all nonrelevant **magenta text** with patient-specific relevant information.

Please see below a list of potential references you may want to consult and cite, based on your clinical judgment and the patient for whom you are seeking payor access.

If you have any questions about the template, reach out to your Field Reimbursement Specialists. If you have any clinical questions about VYEPTI, reach out to your Lundbeck Account Manager or Medical Science Liaison.

**INDICATION**
VYEPTI® is indicated for the preventive treatment of migraine in adults.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

VYEPTI is contraindicated in patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients. Reactions have included anaphylaxis and angioedema.

**WARNINGS AND PRECAUTIONS**

**Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, urticaria, facial flushing, dyspnea, and rash, have occurred with VYEPTI in clinical trials and in the postmarketing setting. Most hypersensitivity reactions occurred during infusion and were not serious, but often led to discontinuation or required treatment. Serious hypersensitivity reactions may occur. Cases of anaphylaxis have been reported in the postmarketing setting. If a hypersensitivity reaction occurs, consider discontinuing VYEPTI, and institute appropriate therapy.

**ADVERSE REACTIONS**

The most common adverse reactions (≥2% and at least 2% or greater than placebo) in the clinical trials for the preventive treatment of migraine were nasopharyngitis and hypersensitivity.

**For more information, please see the accompanying full** [**Prescribing Information**](https://www.lundbeck.com/content/dam/lundbeck-com/americas/united-states/products/neurology/vyepti_pi_us_en.pdf) **and** [**Patient Information**](https://www.lundbeck.com/content/dam/lundbeck-com/americas/united-states/products/neurology/vyepti_ppi_us_en.pdf) **or go to** [**vyeptihcp.com**](https://www.vyeptihcp.com/)**.**

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**VYEPTI is a registered trademark of Lundbeck Seattle BioPharmaceuticals, Inc. EPT-B-101295**

*This following sample letter is for demonstration purposes only. It provides an example of the type of information that may be required when appealing a denial of coverage from a patient’s insurance company. Use of this template or the information in this template does not guarantee coverage. It is not intended to be a substitute for, or to influence the independent clinical decision of, the prescribing healthcare professional.*

[Date] Re:

[Insurance Company Contact] Patient: [Patient’s First and Last Name]

[Insurance Company Name] Subscriber ID #: [Insurance Subscriber ID]

[Insurance Company Address] Subscriber Group #: [Insurance Group ID]

[Insurance Company City, State ZIP] Date of Birth: [Patient’s Date of Birth]

Dear [Insurance Company Contact]:

It has come to my attention that [Patient’s First and Last Name] has been denied the use of VYEPTI® (eptinezumab-jjmr), an intravenous calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults. It is my understanding, based on your letter of denial dated [date of denial letter (prior authorization denial letter #)], that coverage for treatment with VYEPTI was denied because [insert specific reason as stated in the denial letter].

Please accept this letter as [Patient’s First and Last Name]’s appeal to [Insurance Company Name]’s decision to deny coverage for VYEPTI 300mg.

As you know, [Patient’s First and Last Name] was diagnosed with [diagnosis; ICD-10 code] as evidenced by [# of migraine days per month] on [insert date of diagnosis]. [He/She] has utilized [number of doses] doses of VYEPTI [100mg/or 300mg]. Since the initiation of VYEPTI, the patient [has seen a reduction in monthly migraine days]. I’ve also included the history of prior treatments [and treatments attempted,] [(see attachment for chart notes)].

Treatment History

* [Prior treatment name], [treatment start and end date], and [reason for discontinuation]
* List all prior treatments in above format

[Treatments Attempted]

* [Treatment name], [ date], and [reason patient was unable to try treatment due to inability to self-inject, contraindications, etc.]
* List all prior attempts of treatments in above format

However, in accordance with the FDA labeling, and in my medical opinion, this patient would benefit from [initiation / continuation / reapproval] of the 300mg dose to further reduce monthly migraine days (MMDs). It is our [hope/clinical assessment], and as stated in the full Prescribing Information, that this patient may benefit from a dosage of 300 mg. A further reduction in migraine days and migraine severity may have a positive [effect on other abortive medication use, effect on patient functioning, etc.].

Additionally, [Patient] could be at risk of migraine treatment disruption if unable to increase the dosage of VYEPTI to 300mg [If applicable, insert potential risks of disruption to therapy: increased migraine days, additional provider visits, other migraine-related medical care etc.].

Should you require additional information, please do not hesitate to contact my office by calling [Practice Phone Number]. I look forward to receiving your timely response and approval of VYEPTI for [Patient’s First and Last Name].

## Sincerely,

[Physician’s Signature] [Physician’s Name]

[Provider Identification Number] [Name of Practice]

[Phone Number]

**Enclosures:** (attach as appropriate)

* Any original Letter of Medical Necessity
* VYEPTI Prescribing Information
* Patient clinical/diagnostic notes and relevant lab reports
* Published clinical references supporting your letter
* Copies of any migraine assessment or documentation of mean monthly migraine reduction results, e.g., Migraine Disability Assessment (MIDAS), Migraine Physical Function Impact Diary (MPFID), and/or Headache Impact Test (HIT-6)

**Clinical References**

**VYEPTI as treatment in Chronic and Episodic Migraine**

1. [VYEPTI (eptinezumab-jjmr) [package insert]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.](https://www.lundbeck.com/content/dam/lundbeck-com/americas/united-states/products/neurology/vyepti_pi_us_en.pdf)

**Increasing VYEPTI dosage: reference on use of VYEPTI as treatment in Chronic or Episodic Migraine**

1. [Chen H, Luo W. Efficacy and safety of eptinezumab 300mg versus 100mg for migraine patients: a meta-analysis of randomized controlled studies. *Int J Neurosci.* 2022:1-6.](https://pubmed.ncbi.nlm.nih.gov/35993143/)

Chronic:

1. [Kudrow D, Cady RK, Allan B, et al. Long-term safety and tolerability of eptinezumab in patients with chronic migraine: a 2-year, open-label, phase 3 trial. *BMC Neurol.* 2021;21(1):126.](https://pubmed.ncbi.nlm.nih.gov/33740902/)
2. [Lipton RB, Goadsby PJ, Smith J, et al. Efficacy and safety of eptinezumab in patients with chronic migraine: PROMISE-2. *Neurology*. 2020;94:e1365-e1377.](https://pubmed.ncbi.nlm.nih.gov/32209650/)
3. [Ashina M, Lanteri-Minet M, Pozo-Rosich P, et al. Safety and efficacy of eptinezumab for migraine prevention in patients with two-to-four previous preventive treatment failures (DELIVER): a multi-arm, randomised, double-blind, placebo-controlled, phase 3b trial. *Lancet Neurol.* 2022;21:597-607.](https://pubmed.ncbi.nlm.nih.gov/35716692/)

Episodic:

1. [Smith TR, Janelidze M, Chakhava G, et al. Eptinezumab for the prevention of episodic migraine: sustained effect through 1 year of treatment in the PROMISE-2 study. *Clin Ther*. 2020;42(12):2254-2265.e3](https://pubmed.ncbi.nlm.nih.gov/33250209/).
2. [Ashina M, Saper J, Cady R, et al. Eptinezumab in episodic migraine: a randomized, double-blind, placebo-controlled study (PROMISE-1). *Cephalalgia*. 2020;40(3):241-254](https://pubmed.ncbi.nlm.nih.gov/32075406/).

**Reduction in migraine days and response rates: reference on use of VYEPTI as treatment in Chronic and Episodic Migraine**

Chronic:

1. [Silberstein S, Diamond M, Hindiyeh NA, et al. Eptinezumab for the prevention of chronic migraine: efficacy and safety through 24 weeks of treatment in the phase 3 PROMISE-2 (Prevention of migraine via intravenous ALD403 safety and efficacy-2) study. *J Headache Pain*. 2020;21(1):120.](https://pubmed.ncbi.nlm.nih.gov/33023473/)
2. [Lipton RB, Goadsby PJ, Smith J, et al. Efficacy and safety of eptinezumab in patients with chronic migraine: PROMISE-2. *Neurology*. 2020;94:e1365-e1377.](https://pubmed.ncbi.nlm.nih.gov/32209650/)

Episodic:

1. [Smith TR, Janelidze M, Chakhava G, et al. Eptinezumab for the prevention of episodic migraine: sustained effect through 1 year of treatment in the PROMISE-2 study. Clin Ther. 2020;42(12):2254-2265.e3](https://pubmed.ncbi.nlm.nih.gov/33250209/).
2. [Ashina M, Saper J, Cady R, et al. Eptinezumab in episodic migraine: a randomized, double-blind, placebo-controlled study (PROMISE-1). *Cephalalgia*. 2020;40(3):241-254.](https://pubmed.ncbi.nlm.nih.gov/32075406/)

**Acute medication day reduction: reference on use of VYEPTI as treatment in Chronic Migraine**

1. [Silberstein S, Diamond M, Hindiyeh NA, et al. Eptinezumab for the prevention of chronic migraine: efficacy and safety through 24 weeks of treatment in the phase 3 PROMISE-2 (Prevention of migraine via intravenous ALD403 safety and efficacy-2) study. *J Headache Pain*. 2020;21(1):120.](https://pubmed.ncbi.nlm.nih.gov/33023473/)

**Treatment disruption: reference on use of VYEPTI as treatment in Chronic Migraine**

1. [Newman L, Vo P, Zhou L, et al. Health care utilization and costs in patients with migraine who have failed previous preventive treatments. *Neurol Clin Pract.* 2021;11(3):206-215](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8382370/).

**Inadequate migraine treatment: reference on use of VYEPTI as treatment in Chronic Migraine**

1. [Bigal ME, Lipton RB. Migraine chronification. *Curr Neurol Neurosci Rep.* 2011;11(2):139-148.](https://pubmed.ncbi.nlm.nih.gov/21243447/)
2. [Buse DC, Greisman JD, Baigi K, et al. Migraine progression: a systematic review. *Headache*. 2019;59(3):306-338.](https://pubmed.ncbi.nlm.nih.gov/30589090/)
3. [Pozo-Rosich P, Dodick DW, Ettrup A, et al. Shift in diagnostic classification of migraine after initiation of preventive treatment with eptinezumab: post hoc analysis of the PROMISE studies. *BMC Neurol*. 2022;22(1):394.](https://pubmed.ncbi.nlm.nih.gov/36284281/)

**Adjusting treatment to patient needs: reference on use of VYEPTI as treatment in Chronic and Episodic Migraine**

1. [Ailani J, Burch RC, Robbins MS. The American Headache Society consensus statement: update on integrating new migraine treatments into clinical practice. *Headache*. 2021;61(7):1021-1039.](https://pubmed.ncbi.nlm.nih.gov/34160823/)