**Instructions for Use: Letter of Medical Necessity for 300mg Dosage Template with Clinical References**

If your patient’s health insurance provider restricts coverage on VYEPTI® (eptinezumab-jjmr), submission of a letter of medical necessity may help ensure your patients who need VYEPTI are able to receive it. This sample letter will help demonstrate a patient’s need for access to therapy and provide examples of published clinical references based on common payor requirements, which may vary. Inclusion of published clinical references based on patient presentation, and the unique payor requirements identified in the benefits investigation process, may assist the prior authorization submission 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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*The 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]:

I am writing on behalf of my patient, [Patient’s First and Last Name], to demonstrate the medical necessity and support for the coverage of VYEPTI® (eptinezumab-jjmr) 300mg for [Indication and ICD-10 code].

I have read and acknowledge your policy for the responsible management of drugs in this category. This patient will receive treatment for migraine with VYEPTI, which is indicated for preventive treatment of migraine in adults. This letter serves to document that [Patient First and Last Name] needs VYEPTI and that VYEPTI is medically necessary for [him/her]. On behalf of the patient, I am requesting approval for use and subsequent payment for treatment.

Below you will find a description of the patient’s medical history, including prior therapies, and [his/her] current comorbidities and diagnosis.

**Medical History, Diagnosis, and Rationale**

[Patient] is [a/an] [age]-year-old [male/female] diagnosed with [chronic/episodic] migraine disease as evidenced by [# of migraine days per month]. [Patient] has been in my care since [date]. As a result of their migraine disease, my patient [enter brief description of patient history and any comorbidities]. Additionally, [Patient Name] has tried [or attempted] the following previous treatments.

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

Currently my patient [confirm patient has tolerated VYEPTI with minimal or no side effects]. [Patient Name] has had a response to VYEPTI therapy in a decrease in average monthly headache days of at least [fill in % of reduction] compared to [fill in Migraine Disability Assessment (MIDAS) score and/or Migraine Physical Function Impact Diary (MPFID) and/or Headache Impact Test (HIT-6) scores].

Even though my patient has shown [response and reduction in migraine days] with [VYEPTI 100mg], it is our hope that we will successfully further reduce or eliminate [Patient Name’s] migraine headaches, thus restoring a high level of functioning by utilizing VYEPTI 300mg.

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

Based on the above facts, I am confident you will agree that VYEPTI is indicated and medically necessary for this patient. The plan of treatment is to [start/increase the dosage of] the patient on VYEPTI 300mg. Administration of VYEPTI is planned on [DATE] and will be continued approximately every 3 months.

Please contact my office by calling [Practice Phone Number] for any additional information you may require in support of coverage for VYEPTI. I look forward to your timely approval.

## 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/)