**Instructions for Use: Letter of Medical Exception Template (All Doses) with Clinical References**

If your patient’s health insurance provider excludes or has not made a coverage decision on VYEPTI® (eptinezumab-jjmr), a letter of medical exception may be used to ensure that 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, 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 Specialist. 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/)**.**

**© 2023 Lundbeck. All rights reserved.**

**VYEPTI is a registered trademark of Lundbeck Seattle BioPharmaceuticals, Inc. EPT-B-100363v4**

*The following sample letter is for demonstration purposes only. It provides an example of the type of information that may be required when seeking 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 this letter of medical exception on behalf of [Patient’s First and Last Name] to request coverage of VYEPTI® (eptinezumab-jjmr) [100mg/300mg] for the preventive treatment of migraine in adults [ICD-10 Code].

I acknowledge that your policy currently excludes VYEPTI for the prevention of migraine in favor of other therapies. However, in the best interest of the patient and my clinical opinion, I am requesting that an exception be made for [Patient’s First and Last Name]. This letter provides the clinical rationale and relevant information about the patient’s medical history and treatment that supports the use of VYEPTI.

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

In my medical judgment, this patient is an appropriate candidate for treatment with VYEPTI. Based on the above information, you can see that VYEPTI is medically necessary, and the patient and I appreciate you overturning your exclusion for this medication. I have included the US Food and Drug Administration (FDA) approval letter for VYEPTI as well as supporting clinical data. If coverage is still in question, I request an expedited exception and review of this documentation by a neurologist specializing in the treatment of migraine.

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

Sincerely,

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

[Provider Identification Number] [Name of Practice]

[Phone Number]

**Enclosures:** (attach as appropriate)

|  |  |
| --- | --- |
| * US Food and Drug Administration (FDA) approval letter for VYEPTI
* 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)

2. [U.S. Food and Drug Administration. VYEPTI BLA Approval. February 21, 2020. Accessed July 18, 2023.](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/761119Orig1s000ltr.pdf)

**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](https://pubmed.ncbi.nlm.nih.gov/33023473/) [treatment in the phase 3 PROMISE-2 (Prevention of migraine via intravenous ALD403 safety and efficacy-2) study. *J Headache Pain*.](https://pubmed.ncbi.nlm.nih.gov/33023473/) [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*.](https://pubmed.ncbi.nlm.nih.gov/32209650/) [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](https://pubmed.ncbi.nlm.nih.gov/33250209/) [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).](https://pubmed.ncbi.nlm.nih.gov/32075406/)

[*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](https://pubmed.ncbi.nlm.nih.gov/33023473/) [treatment in the phase 3 PROMISE-2 (Prevention of migraine via intravenous ALD403 safety and efficacy-2) study. *J Headache Pain*.](https://pubmed.ncbi.nlm.nih.gov/33023473/) [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.](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8382370/)

[*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](https://pubmed.ncbi.nlm.nih.gov/36284281/) [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](https://pubmed.ncbi.nlm.nih.gov/34160823/) [clinical practice. *Headache*. 2021;61(7):1021-1039.](https://pubmed.ncbi.nlm.nih.gov/34160823/)

**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](https://pubmed.ncbi.nlm.nih.gov/35993143/) [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,](https://pubmed.ncbi.nlm.nih.gov/33740902/) [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*.](https://pubmed.ncbi.nlm.nih.gov/32209650/) [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](https://pubmed.ncbi.nlm.nih.gov/35716692/) [previous preventive treatment failures (DELIVER): a multi-arm, randomised, double-blind, placebo-controlled, phase 3b trial. *Lancet Neurol.*](https://pubmed.ncbi.nlm.nih.gov/35716692/)[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](https://pubmed.ncbi.nlm.nih.gov/33250209/) [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).](https://pubmed.ncbi.nlm.nih.gov/32075406/)

[*Cephalalgia*. 2020;40(3):241-254](https://pubmed.ncbi.nlm.nih.gov/32075406/).