Guide to Using Sample Medical Necessity/Exception and Appeals Letters for Patients Prescribed VYEPTI

This document contains **2 letter templates** that you may edit and send to your patients' health plans to secure prior authorizations, medical exceptions, appeals and/or reauthorizations.

INSTRUCTIONS

Letter of Medical Necessity/Exception Template (100 mg & 300 mg)
If your patient's health insurance provider restricts, excludes, or has not yet made a coverage decision on VYEPTI, submission of a Letter of Medical Necessity/Exception may help your eligible patients receive their VYEPTI as prescribed. This sample letter can help document a patient's need for access to therapy, and this guide provides examples of published clinical references based on common payer requirements, which may vary. Inclusion of published clinical references based on patient presentation, and the unique payer requirements identified in the benefits investigation process, may assist the request for coverage for your patient.

Letter of Appeal Template (100 mg & 300 mg)
If your patient's health insurance provider denies coverage, you may explain your clinical rationale for prescribing VYEPTI through a Letter of Appeal. This sample letter can help document a patient's need for access to therapy, and this guide provides examples of published clinical references, which may support the prior authorization submission for VYEPTI for your patient.

To use the templates:

Replace magenta text with relevant patient-specific information. When finished, make sure to delete any remaining or unused language still in magenta text.

On the last page of this document, please see 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 payer access. For your convenience, the references are available as a set package to enclose with your letter. Please double check links and references before using.

If you have any questions about the templates, reach out to a Field Access Specialist. If you have any clinical questions about VYEPTI, reach out to your Lundbeck Biopharmaceutical Account Manager or Medical Science Liaison.

For additional access resources, please visit vyeptihcp.com/access-vyepti.

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.

Hypertension: Development of hypertension and worsening of pre-existing hypertension have been reported following the use of CGRP antagonists, including VYEPTI, in the postmarketing setting. Some of the patients who developed new-onset hypertension had risk factors for hypertension. There were cases requiring initiation of pharmacological treatment for hypertension, and in some cases hospitalization. Hypertension may occur at any time during treatment, but was most frequently reported within 7 days of therapy initiation. The CGRP antagonist was discontinued in many of the reported cases.

Monitor patients treated with VYEPTI for new-onset hypertension or worsening of pre-existing hypertension, and consider whether discontinuation of VYEPTI is warranted if evaluation fails to establish an alternative etiology or blood pressure is inadequately controlled. (continued)

Please see additional Important Safety Information throughout. For more information, please see the Full **Prescribing Information** and **Patient Information** or go to **vyeptihcp.com**.

The following sample letters are for demonstration purposes only. They provide examples of the types of information that may be required when seeking coverage from a patient's insurance company. Use of these templates or the information in these templates does not guarantee coverage. They are not intended to be a substitute for, or to influence the independent clinical decision of, the prescribing healthcare professional.

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(eptinezumab-jjmr)
100 mg/mL Injection for IV

Below is a template you can use to draft your Letter of Medical Necessity/Exception.

Fill out this letter to support coverage for patients who need to initiate, continue, or escalate their dose of VYEPTI.

Click here to download the template

Include patient's name, date of birth, and insurance subscriber ID number and group number

Show evidence for diagnosis and patient need using examples such as # of migraine days and MIDAS, MPFID, and/or HIT-6 scores

Fill out only if your patient is starting VYEPTI (VYEPTI 100 mg or 300 mg)

Fill out only if your patient requires a higher dose of VYEPTI (VYEPTI 300 mg)

Fill out only if your patient needs to continue VYEPTI (VYEPTI 100 mg or 300 mg)

Once completed, remove unused sections, copyright language, and unfilled magenta placeholders

[Letter of Medical Necessity/Exception Template]

[Date]
[Insurance Company Contact]

[Insurance Company Name]
[Insurance Company Address]
[Insurance Company City, State ZIP]

Re:
Patient: [Patient's First and Last Name]

Subscriber ID #: [Insurance Subscriber ID]
Subscriber Group #: [Insurance Group ID]
Date of Birth: [Patient's Date of Birth]

Dear [Insurance Company Contact]:

I am writing this [Letter of Medical Necessity/Letter of Medical Exception] on behalf of my patient, [Patient's First and Last Name], to support coverage of VYEPTI® (eptinezumab-jjmr) [100 mg/300 mg] for the preventive treatment of migraine in adults [ICD-10 code].

[I have read and acknowledge your policy for the responsible management of drugs in this category] or [I acknowledge that your policy currently excludes VYEPTI for the prevention of migraine in favor of other therapies]. This letter serves to document that VYEPTI is medically necessary for [Patient First and Last Name]. On behalf of the patient, I am requesting [approval/an exception] for use in this case.

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

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 migraine history as well as clinical evidence. Examples include:

- Baseline and current number of migraine days per month
- Baseline and current Migraine Disability Assessment (MIDAS) and/or Migraine Physical Function Impact Diary (MPFID) and/or Headache Impact Test (HIT-6) scores
- 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 (e.g., intolerance, lack of efficacy)]
- List all prior treatments in above format.
- List any treatments patient was unable to try due to inability to self-inject, contraindications, etc.
- List the status of current treatments that may continue following initiation or continuation of VYEPTI

[Initiation of 100mg or 300 mg]:
Based on my patient's treatment history and in accordance with the FDA labeling, it is my medical opinion that this patient would benefit from initiation of VYEPTI [100 mg or 300 mg] dose to reduce monthly migraine days (MMDs) and migraine severity. It is my clinical assessment that a reduction in migraine days and migraine severity will have a positive [effect on other abortive medication use, effect on patient functioning, etc.].

[Dose escalation to 300mg only]:
Even though my patient has shown [response and reduction in migraine days] with VYEPTI 100 mg, it is my clinical assessment that we will successfully further reduce or potentially eliminate [Patient Name's] migraine headaches, thus restoring a high level of functioning by utilizing VYEPTI 300 mg.

[Continuation of 100 mg/300 mg]:
Currently my patient [confirm patient has tolerated VYEPTI with minimal or no side effects]. [Patient Name] has had a response to VYEPTI therapy as measured by a reduction in [# of migraine days per month and/or Migraine Disability Assessment (MIDAS) and/or Migraine Physical Function Impact Diary (MPFID) and/or Headache Impact Test (HIT-6) scores].

Additionally, [Patient] could be at risk of migraine treatment disruption if unable to [increase the dosage of VYEPTI/initiate VYEPTI/continue VYEPTI] [If applicable, insert potential risks of disruption to therapy: e.g., 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/continue] the patient [on/to] VYEPTI [100 mg/300 mg]. 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]
[Provider Identification Number]
[Phone Number]

[Physician's Name]
[Name of Practice]

Enclosures: (attach as appropriate)

- Any original Letter of Medical Necessity
- Patient clinical/diagnostic notes and relevant lab reports
- Published clinical references supporting your letter

WARNINGS AND PRECAUTIONS (continued)

Raynaud's Phenomenon: Development of Raynaud's phenomenon and recurrence or worsening of pre-existing Raynaud's phenomenon have been reported in the postmarketing setting following the use of CGRP antagonists. In reported cases with monoclonal antibody CGRP antagonists, symptom onset occurred a median of 71 days following dosing. Many of the cases reported serious outcomes, including hospitalizations and disability, generally related to debilitating pain. In most reported cases, discontinuation of the CGRP antagonist resulted in resolution of symptoms. (continued)

Please see additional Important Safety Information throughout. For more information, please see the Full Prescribing Information and Patient Information or go to vyeptihcp.com.

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(eptinezumab-jjmr)
100 mg/mL Injection for IV

Below is a template you can use to draft your Letter of Appeal.

Fill out this letter if your patient was denied for initiation, continuation, or escalation of VYEPTI.

Click here to download the template

Include patient's name, date of birth, and insurance subscriber ID number and group number

Show evidence for diagnosis using examples such as # of migraine days and MIDAS, MPFID, and/or HIT-6 scores

Only fill out this section if your patient is continuing the previous dose of VYEPTI or seeking a higher dose (VYEPTI 300 mg)

Once completed, remove unused sections, copyright language, and unfilled magenta placeholders

[Letter of Appeal Template]

[Date]
[Insurance Company Contact]
[Insurance Company Name]
[Insurance Company Address]
[Insurance Company City, State ZIP]

Re:
Patient: [Patient's First and Last Name]
Subscriber ID #: [Insurance Subscriber ID]
Subscriber Group #: [Insurance Group ID]
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 [100 mg/300 mg] 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 [100 mg/300 mg].

As you know, [Patient's First and Last Name] was diagnosed with [diagnosis; ICD-10 code] as evidenced by [examples include: # of migraine days per month and/or Migraine Disability Assessment (MIDAS) and/or Migraine Physical Function Impact Diary (MPFID) and/or Headache Impact Test (HIT-6) scores] on [insert date of diagnosis].

[Continuation of therapy or dose escalation only]
[Patient's First and Last Name] has utilized [number of doses] doses of VYEPTI [100 mg/300 mg]. Since the initiation of VYEPTI, the patient [examples include: has seen a reduction in migraine days and/or Migraine Disability Assessment (MIDAS) and/or Migraine Physical Function Impact Diary (MPFID) and/or Headache Impact Test (HIT-6) scores]. 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 (e.g., intolerance/lack of efficacy)]
- List all prior treatments in above format.
- List any treatments patient was unable to try due to inability to self-inject, contraindications, etc.

However, based on my patient's treatment history and in accordance with the FDA labeling, it is my medical opinion that this patient would benefit from [initiation/continuation/reapproval] of the [100 mg/300 mg] dose to [further reduce/maintain reduction in] monthly migraine days (MMDs) and migraine severity. It is my clinical assessment that a [further/maintained] 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 [initiate/continue/increase] the dosage of VYEPTI [at/to] [100 mg/300 mg]. [If applicable, insert potential risks of disruption to therapy: e.g., increased migraine days, additional provider visits, other migraine-related medical care etc.]. If coverage is still in question, I'd like to request a review of this documentation by a neurologist specializing in the treatment of migraine.

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]
[Provider Identification Number]
[Phone Number]

[Physician's Name]
[Name of Practice]

Enclosures: (attach as appropriate)
- Any original Letter of Medical Necessity
- Patient clinical/diagnostic notes and relevant lab reports
- Published clinical references supporting your letter

WARNINGS AND PRECAUTIONS

Raynaud's Phenomenon (continued): VYEPTI should be discontinued if signs or symptoms of Raynaud's phenomenon develop, and patients should be evaluated by a healthcare provider if symptoms do not resolve. Patients with a history of Raynaud's phenomenon should be monitored for, and informed about the possibility of, worsening or recurrence of signs and symptoms.

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.
Please see additional Important Safety Information throughout.

For more information, please see the Full **Prescribing Information** and **Patient Information** or go to **vyeptihcp.com**.

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Clinical References

VYEPTI as treatment in Chronic and Episodic Migraine

1. VYEPTI (eptinezumab-jjmr) [package insert]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.
2. Charles AC, Digre KB, Goadsby PJ, et al. American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: an American Headache Society position statement update. *Headache*. 2024 ;64(4):333-341.

Reduction in migraine days and response rates with VYEPTI 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.
2. Lipton RB, Goadsby PJ, Smith J, et al. Efficacy and safety of eptinezumab in patients with chronic migraine: PROMISE-2. *Neurology*. 2020;94(13):e1365-e1377.
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.

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-1 study. *Clin Ther*. 2020;42(12):2254-2265.e3.
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.

Acute medication day reduction with VYEPTI 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.
2. Marmura MJ, Diener HC, Cowan RP, et al. Preventive migraine treatment with eptinezumab reduced acute headache medication and headache frequency to below diagnostic thresholds in patients with chronic migraine and medication-overuse headache. *Headache*. 2021;61(9):1421-1431.

Increasing VYEPTI dosage to 300 mg in Chronic and Episodic Migraine

1. Chen H, Luo W. Efficacy and safety of eptinezumab 300mg versus 100 mg for migraine patients: a meta-analysis of randomized controlled studies. *Int J Neurosci*. 2022:1-6.
2. 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(7):597-607.
3. Ashina M, Tepper SJ, Gendolla A, et al. Long-term effectiveness of eptinezumab in patients with migraine and prior preventive treatment failures extension of a randomized controlled trial. *J Headache Pain*. 2023;24(1):155.

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.
2. Blumenfeld A, Ettrup A, Hirman J, et al. Long-term reductions in disease impact in patients with chronic migraine following preventive treatment with eptinezumab. *BMC Neurol*. 2022;22(1):251.
3. Lipton RB, Goadsby PJ, Smith J, et al. Efficacy and safety of eptinezumab in patients with chronic migraine: PROMISE-2. *Neurology*. 2020;94(13):e1365-e1377.

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-1 study. *Clin Ther*. 2020;42(12):2254-2265.e3.
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.

Treatment persistence with VYEPTI in Chronic and Episodic Migraine

1. Charleston L 4th, Talon V, Sullivan C, et al. Persistence to anti-CGRP monoclonal antibodies and onabotulinumtoxinA among patients with migraine: a retrospective cohort study. *J Headache Pain*. 2023.24(1):101.

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.

Inadequate migraine treatment in Chronic and Episodic Migraine

1. Bigal ME, Lipton RB. Migraine chronification. *Curr Neurol Neurosci Rep*. 2011;11(2):139-148.
2. Buse DC, Greisman JD, Baigi K, et al. Migraine progression: a systematic review. *Headache*. 2019;59(3):306-338.
3. 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.

Adjusting treatment to patient needs 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.

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