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VYEPTI Access Guide

Key information to support your patients
after VYEPTI is prescribed

For more information, please see the accompanying Full [Prescribing Information](#) and [Patient Information](#) or go to vyepthcp.com.

Introduction

This guide provides key information to help facilitate patient access to VYEPTI after it has been prescribed.



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Potential Access Journey for VYEPTI

VYEPTI CONNECT[®] offers VYEPTI Patient Navigator and Nurse Educators, coverage investigation, in-network infusion location identification and financial assistance options for eligible patients.*

BEFORE INFUSION

The following steps may be done by the patient's provider if infusing on site or the infusion site provider if the patient is referred to another location for their infusion.

1

Conduct a benefits verification

Select a site of care

2

Navigate the prior authorization (PA) process

3

Schedule the patient's infusion

Order and acquire VYEPTI

AFTER INFUSION

4

Submit a claim for reimbursement

5

Schedule the patient's next appointment

Please contact a VYEPTI Field Access Specialist for specific questions about the VYEPTI access journey.

To learn from expert office practice managers and their experience with VYEPTI, please view the webinar, "Expert office managers and a migraine specialist discuss helping patients along their treatment journey" at vyeptihcp.com/access

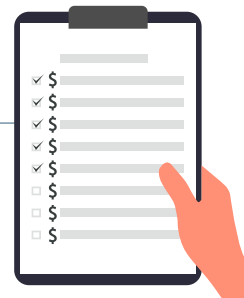
*VYEPTI CONNECT[®] support is only available to patients who enroll; support may vary based on patient eligibility. Please see full [Terms and Conditions](#).

For more information, please see the accompanying Full [Prescribing Information](#) and [Patient Information](#) or go to vyeptihcp.com.

Benefits Verification

Conducting a benefits verification can help identify:

- ✓ Insurance coverage requirements and site of care considerations
 - Some healthcare plans may require additional authorizations for infusion providers that do not align with their site of care policy, such as hospital and hospital outpatient settings
- ✓ Patient financial responsibility, including deductible, coinsurance and/or copay, and annual OOP maximum
- ✓ Out-of-network considerations
- ✓ Billing and coding requirements including NDC, ICD-10, and CPT codes; clinical records; and drug invoices
- ✓ Initial and reauthorization timeframes
- ✓ Drug acquisition options



If VYEPTI is not covered by your patient's healthcare plan, a medical exception can be requested using a [letter of medical necessity/exception](#)

Questions getting a patient started? [VYEPTI CONNECT](#)[®] provides consistent, tailored support throughout the treatment journey.

The following sample letters are intended to be used as guides, and it is important to tailor them to the specific needs of your patient and address the reason(s) why the prescribed treatment is appropriate. They do not guarantee coverage and should not be a substitute for independent clinical decision-making by the prescriber.

Please review your patient's VYEPTI healthcare plan coverage for both the drug component and the administration component. An infusion is typically billed to the medical benefit

CPT, Current Procedural Terminology; ICD-10, International Classification of Diseases, 10th Revision; NDC, National Drug Code; OOP, out of pocket; PA, prior authorization.

For more information, please see the accompanying [Full Prescribing Information](#) and [Patient Information](#) or go to [vyepthcp.com](#).



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Benefits Verification (cont'd)

Considerations for Medicare and Medicaid patients

- For **Medicare patients**, while VYEPTI may be typically processed under the medical benefit (Part B),¹ there are instances in which it may be processed under pharmacy benefit (Part D) and some Medicare Advantage Part C plans. Please contact the healthcare plan directly to determine how they process VYEPTI
- For **Medicaid patients**, VYEPTI coverage may vary by state and may be plan specific. If covered, VYEPTI may be covered under the medical benefit or pharmacy benefit



VYEPTI Coverage Finder can help provide coverage details for VYEPTI in your area

Majority of commercial patients nationwide are covered for VYEPTI after one branded medication or less*

SEARCH

MEDICAL

PHARMACY

Showing Medical coverage for VYEPTI in:

Search Plans

SHOW ALL

COMMERCIAL

MEDICARE

MEDICAID

Plan name	Plan type	Coverage	Prior authorization	Step therapy	Plan details
UnitedHealthcare Advantage 3 Tier PPO	Commercial	Covered PA & ST	Yes	Yes	Show Details
Aetna Standard PPO	Commercial	Covered PA & ST	Yes	Yes	Show Details
Anthem BCBS Essential PPO 4 Tier	Commercial	Covered PA & ST	Yes	Yes	Show Details

Source: Managed Markets Insight and Technology, LLC™, a trademark of MMIT.

Results shown for illustrative purposes.

This coverage tool provides medical and pharmacy benefit coverage of VYEPTI in the selected geography. It is for informational purposes only. Other options for prescription access may be available for your patients. Call VYEPTI CONNECT® at [833-4-VYEPTI](tel:833-4-VYEPTI) to learn more.

Please visit vyepthcp.com/coverage-finder to learn more about VYEPTI coverage including plan details on authorization requirements for your patients

PA, prior authorization.

*The Statement represents the percentage of commercially insured patients with plans providing VYEPTI medical benefit coverage after 1 or fewer trials of a branded medication.

For more information, please see the accompanying Full [Prescribing Information](#) and [Patient Information](#) or go to vyepthcp.com.



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Sites of Care

	VYEPTI Infusion Network		Provider's Office
	Infusion Locations Stand-alone or part of a local hospital or healthcare system		Home Infusion

When selecting the best infusion location for a patient, it is important to consider affordability alongside convenience, as some healthcare plans have different coverage and costs based on site of care.²

Use the [VYEPTI Infusion Locator](#) to help identify infusion options near your patients

VYEPTI Infusion Network

Lundbeck partners with a network of infusion providers to deliver a consistent VYEPTI treatment experience in a convenient location for your patients.

With the VYEPTI Infusion Network, your patients can expect*:



Touchpoints to keep the prescriber informed pre- and post-treatment, including next infusion date



Help enrolling in the VYEPTI CONNECT[®] Copay Assistance Program[†]



Assistance with benefits investigations and prior authorizations

Patients can also expect a welcome phone call from the infusion provider, which may come from an unrecognized number. Please remind patients to be aware of this upcoming call.

VYEPTI INFUSION NETWORK PROVIDERS INCLUDE:


P: 888-777-1945


P: 629-258-2240


option care health[®]
P: 844-789-3784


PARAGON
HEALTHCARE
P: 877-365-5566


P: 615-278-3350


P: 877-488-4825


P: 720-902-4111

Home infusion may be an option, depending on your patient's insurance coverage.
IVX Health, Infusion for Health, and Vivo Infusion only consist of outpatient infusion sites.

For more details on the VYEPTI Infusion Network and to download VYEPTI Infusion Network referral forms, please click [here](#).

VYEPTI CONNECT[®] can assist eligible patients in coordinating with an infusion location (please click [here](#) for more information).

VYEPTI administration is not limited to the VYEPTI Infusion Network; Lundbeck does not recommend use of a specific infusion provider.

*Other infusion providers may also have these offerings.

[†]For eligible patients with commercial insurance.

For general questions about the VYEPTI Infusion Network, please contact your VYEPTI Sales Representative. If you don't have their contact information, click [here](#).

For more information, please see the accompanying Full [Prescribing Information](#) and [Patient Information](#) or go to [vyeptihcp.com](#).



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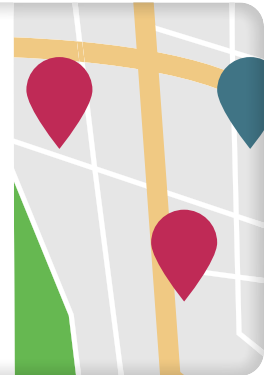
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The VYEPTI Infusion Locator can help identify infusion options, near your patients

Some healthcare plans may require VYEPTI to be infused in certain sites of care or by specific in-network infusion providers in order to be covered, which can also impact cost

Please visit the [VYEPTI Infusion Locator Tool](#)



When referring patients to an infusion site

Help avoid delays for your patient

- ▶ Ensure the referral form is completed with all the required information
 - Include a copy of the patient's medical and prescription insurance cards (front and back)
 - Attach chart notes including migraine history (number of headache and migraine days per month) and medication history (including all treatments tried, failed, or discontinued, along with reasons) that satisfies the patient's insurance requirements



Remind patients that they may receive a welcome phone call from the infusion provider, which could be from a number they don't recognize

When infusing on site

Help avoid delays for your patient and site

- ▶ 1. [Confirm insurance coverage](#)
- ▶ 2. [Order VYEPTI](#) and arrange shipment.
 - For eligible commercially insured patients, enroll them in the [VYEPTI CONNECT[®] Copay Assistance Program](#)
- ▶ 3. After administration, collect your patient's OOP cost and [submit a claim](#)

[VYEPTI CONNECT[®]](#) provides consistent, tailored patient support throughout the treatment journey.



Review the [options for acquiring VYEPTI](#) and select an option, that is in-line with the patients' healthcare plan

If a PA is required for VYEPTI or for a specific site of care, follow up on status with the healthcare plan and confirm infusion timing with the patient upon PA approval

OOP, out of pocket; PA, prior authorization.

For more information, please see the accompanying [Full Prescribing Information](#) and [Patient Information](#) or go to [vyeptihcp.com](#).

Navigating the PA Process



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1

Determine [healthcare plan requirements](#) for both VYEPTI and site of care, including any required supporting documentation

If VYEPTI is not covered by the healthcare plan, a medical exception may be requested using a [letter of medical necessity/exception](#)

2

Complete the appropriate electronic or written PA form for the healthcare plan

- ▶ Most PAs for VYEPTI include
- Baseline and current migraine information
 - Number of headaches and migraine days per month
 - MIDAS, MPFID, or HIT-6 scores
 - Comorbidities
 - Tried, failed, and discontinued medications

- ▶ Include most recent clinical notes to support your request

PA requests are often denied due to incomplete or inaccurate information. Ensuring all details are provided may improve time to approval

3

If PA or medical exception is denied, the decision may be appealed using a [letter of appeal](#)

The following sample letters are intended to be used as guides, and it is important to tailor them to the specific needs of your patient and address the reason(s) why the prescribed treatment is appropriate. They do not guarantee coverage and should not be a substitute for independent clinical decision making by the prescriber.

Please utilize the [PA checklist](#) to help organize information that may be required for a PA, and visit vyeptihcp.com/access to access additional resources that may be helpful

This checklist is informational and is not intended to reflect the specific requirements of any health plan. It does not guarantee coverage and is not a substitute for independent clinical decision making by the prescriber.

HIT-6, headache impact test; MIDAS, Migraine disability assessment; MPFID, migraine physical function impact diary; PA, prior authorization.

For more information, please see the accompanying [Full Prescribing Information](#) and [Patient Information](#) or go to vyeptihcp.com.

Navigating the PA Process (cont'd)

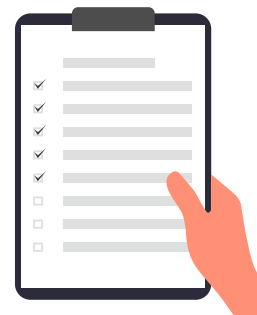
Key PA process considerations when referring patients to an infusion location

- ▶ VYEPTI Infusion Network sites and other infusion locations may assist with the PA process, but offices should confirm this during the referral process
- ▶ If the infusion location does not assist with the PA process, then the referring provider would submit the PA and continue to follow up until PA decision
- ▶ Proactive communication between the provider's office and infusion location is key to ensuring seamless coordination



Key considerations when handling reauthorization, when clinically appropriate

- ▶ Determine if the patient's healthcare plan requires reauthorization for VYEPTI, administration services, and/or the site of care
- ▶ If so, confirm continued medical necessity, collect updated clinical information,* and submit a reauthorization request/form
 - Reauthorization checklist
 - ✓ Prior to expiration of current authorization, review payer drug policy to determine reauthorization criteria
 - ✓ Submit reauthorization form in conjunction with clinical documentation as requested in drug policy
 - ✓ Follow up with healthcare plan on submission status if determination hasn't been made/communicated
- ▶ Ensure patient's next infusion is scheduled



PA, prior authorization.

*Examples of clinical information to support reauthorization could include: migraine days per month, migraine frequency, headache days per month, headache pain intensity, and acute/rescue medication use.

For more information, please see the accompanying Full Prescribing Information and Patient Information or go to [vyepthcp.com](https://www.vyepthcp.com).



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PA Checklist for VYEPTI

This checklist is for informational purposes only and can help organize information that may be required for the patient's insurance. It does not guarantee reimbursement of coverage, and is not intended to be a substitute for, or to influence, the independent clinical decision of the prescriber.

Step 1 Insurance Investigation

To understand the PA requirements for each plan, offices must contact the insurance providers, as different plans may have different requirements

PA considerations vary between plans, including processes, step requirements, duration of approval, and other relevant information.

Step 2 Patient/Provider Information

Name: _____ Date of birth: _____

Insurance plan: _____

Specialist, or specialist consulted: _____ Provider ID number: _____

☐ Initial Authorization Request ☐ Reauthorization Request (Complete the following items)

- Reauthorization criteria: _____

- Has the patient experienced a reduction in migraine: frequency, duration, and migraine free days due to therapy? _____

Some plans may require documents to support the PA, including a copy of your patient's chart notes.

Step 3 Diagnosis/Treatment Information

Diagnosis/I

Dose: ☐ 1

Symptoms

Headache

Headache

Nausea/Vo

Photophob

Unilateral h

Pulsating/T

Moderate/s

Aggravated

stairs/Phys

Other: _____

ICD-10-CM=I

Tenth Revisi

Preventive Examples

Anti-CGRPs*	Angiotensin-Converting Enzyme Inhibitors/Angiotensin II Receptor Blockers	Antidepressants	Antiepileptics/Anticonvulsants	Beta-blockers	Calcium Channel Blockers
Aimovig® (erenumab-aooe)	Candesartan	Amitriptyline	Divalproex sodium	Atenolol	Diltiazem
Ajovy® (fremanezumab-vfrm)	Enalapril	Citalopram	Gabapentin	Metoprolol	Nifedipine
Emgality® (galcanezumab-gnlm)	Irbesartan	Doxepin	Topiramate	Nadolol	Nimodipine
Nurtec ODT® (rimegepant)	Lisinopril	Fluoxetine	Valproic acid	Propranolol	Verapamil
Qulipta® (atogepant)	Losartan	Fluvoxamine		Timolol	
VYEPTI® (eptinezumab-jjmr)	Olmesartan	Mirtazapine			
	Ramipril	Nortriptyline			
	Valsartan	Paroxetine			
		Protriptyline			
		Sertraline			
		Venlafaxine			

Acute/Abortive Examples

NSAIDs/Analgesics	Ergot Alkaloid	Derivative Triptans	Combination/Other	Anti-CGRPs*
Acetaminophen	Ergotamine	Almotriptan	Acetaminophen/aspirin/caffeine	Nurtec ODT® (rimegepant)
Aspirin	Dihydroergotamine	Eletriptan	Butalbital/acetaminophen/caffeine	Ubrelyv® (ubrogepant)
Diclofenac		Frovatriptan	Butalbital/aspirin/caffeine	
Ibuprofen		Naratriptan	Butorphanol	
Naproxen		Rizatriptan	Ergotamine/caffeine	
		Sumatriptan	Sumatriptan/naproxen	
		Zolmitriptan		

Download the PA Checklist

CGRP, calcitonin gene-related peptide; NSAIDs, non-steroidal anti-inflammatory drugs; ODT, orally disintegrating tablet; PA, prior authorization.

*Brand names utilized as there is a lack of generic and biosimilar availability for these products. All trademarks are property of their respective owners.

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



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Ordering

There are 2 ways to order VYEPTI

1

2

Buy-and-Bill via Specialty Distributor

Specialty distributors included in Lundbeck's network

cencora	ASD Healthcare	P: 800-746-6273	F: 800-547-9413
	Besse Medical	P: 800-543-2111	F: 800-543-8695
	Oncology Supply	P: 800-633-7555	F: 800-248-8205
MCKESSON	Plasma & Biologics	P: 877-625-2566	F: 888-752-7626
	Specialty Care Division	P: 855-477-9800	F: 800-800-5673
	Oncology and Urology	P: 877-453-3972	F: 877-274-9897
 CardinalHealth™	Hospitals	P: 855-855-0708	F: 614-553-6301
	Metro Medical™	P: 800-768-2002	
 CuraScriptSD® CARING FOR THOSE WHO CARE	CuraScript Specialty Distribution	P: 877-599-7748	F: 800-862-6208

The specialty distributor will ship VYEPTI to your site, typically within 1 business day.

Click [here](#) for information on VYEPTI billing codes

Lundbeck does not recommend the use of any particular specialty distributor.

For more information, please see the accompanying Full [Prescribing Information](#) and [Patient Information](#) or go to vyepthcp.com.

Ordering (cont'd)

There are 2 ways to order VYEPTI



Send a prescription to a Specialty Pharmacy

Specialty pharmacies included in Lundbeck's network



P: 844-789-3784

F: 844-325-0618



P: 800-259-7145

F: 877-892-3019

To download the referral forms for each specialty pharmacy, click the logos above

The specialty pharmacy will coordinate shipment details based on the infusion schedule with your infusion site.

Ordering requirements, which can be determined during the benefits verification process, may differ based on the patient's healthcare plan coverage

To Help Avoid Treatment Delays



Communicate with the specialty pharmacy

- It's important for you or the infusion site to communicate with the specialty pharmacy in case more information is needed to verify your patients' coverage and to coordinate shipments



Prepare your patients

- Your patients will be contacted directly for permission to ship VYEPTI
 - Remind your patients it's important to answer calls from the specialty pharmacy or to promptly call them back
- To avoid the call appearing as "unknown," please have your patients add the specialty pharmacy number to their phone contacts

Lundbeck does not recommend the use of any particular specialty pharmacy.

For more information, please see the accompanying Full [Prescribing Information](#) and [Patient Information](#) or go to vyepthcp.com.



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Claims Submission



To start a claim, submit a copy of the CMS Form 1500 or UB-04 Claim Form and a copy of the explanation of payment or explanation of benefits from the patient's insurance carrier(s).

For information on submitting a VYEPTI CONNECT[®] Copay Assistance claim, click [here](#).

Common Reasons for Claim Denials

Claims may be denied due to incomplete or inaccurate information, including:

- Incorrect ICD-10/CPT[®]/HCPCS code(s)
- Incorrect number of units billed
- Missing or abbreviated policy numbers
- Missing NDC number
- Missing PA on file/inaccurate PA number

This information is for reference only and is not intended to serve as reimbursement or legal advice, a guarantee of coverage, or a guarantee of payment for VYEPTI. Coding is a clinical decision, and all coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement.

Considerations for Medicaid and Medicare patients



- For **Medicaid** patients OOP costs can vary based on state and patient income^{3,4}
- For **Medicare** patients
 - OOP costs can vary depending on type of Medicare (original Medicare/Medicare Advantage)^{3,4}
 - Each site of care location may have its own billing codes and rules for covered services⁵
 - For **Original Medicare**, infusion is covered under Part B at providers' offices or infusion locations¹
 - **Note:** If billing through Part B, a provider must be on site. If a provider is not on site, the visit will be billed to Part D
 - For **Medicare Advantage**, infusion can be covered under Part C for providers' offices or infusion locations or Part D for home infusion^{3*}

Please contact a VYEPTI Field Access Specialist for specific questions about claims submissions or denials.

CMS, Centers for Medicare & Medicaid Services; CPT[®], Current Procedural Technology; HCPCS, Healthcare Common Procedure Coding System; ICD-10, International Classification of Diseases, 10th Revision; NDC, National Drug Code; OOP, out of pocket; PA, prior authorization.

*Lundbeck does not recommend use of any specific infusion provider.

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

Codes That May Help With Billing and Reimbursement

Below is a list of codes that may be useful for VYEPTI billing and reimbursement. It is important to note that the codes listed here may not be inclusive of all codes that may be applicable. The use of the following codes does not guarantee reimbursement.

ICD-10^{5,6}

Migraine Without Aura G43.0		
Migraine without aura, without status migrainosus	NOT INTRACTABLE G43.009	INTRACTABLE G43.019
Migraine without aura, with status migrainosus	NOT INTRACTABLE G43.001	INTRACTABLE G43.011
Migraine With Aura G43.1		
Migraine with aura, without status migrainosus	NOT INTRACTABLE G43.109	INTRACTABLE G43.119
Migraine with aura, with status migrainosus	NOT INTRACTABLE G43.101	INTRACTABLE G43.111
Chronic Migraine Without Aura G43.7		
Chronic migraine without aura, without status migrainosus	NOT INTRACTABLE G43.709	INTRACTABLE G43.719
Chronic migraine without aura, with status migrainosus	NOT INTRACTABLE G43.701	INTRACTABLE G43.711
Other Migraine, Menstrual Migraine G43.8		
Other migraine, without status migrainosus	NOT INTRACTABLE G43.809	INTRACTABLE G43.819
Other migraine, with status migrainosus	NOT INTRACTABLE G43.801	INTRACTABLE G43.811
Migraine, Unspecified G43.9		
Migraine, unspecified, without status migrainosus	NOT INTRACTABLE G43.909	INTRACTABLE G43.919
Migraine, unspecified, with status migrainosus	NOT INTRACTABLE G43.901	INTRACTABLE G43.911
Chronic Migraine With Aura G43.E		
Chronic migraine with aura, without status migrainosus	NOT INTRACTABLE G43.E09	INTRACTABLE G43.E19
Chronic migraine with aura, with status migrainosus	NOT INTRACTABLE G43.E01	INTRACTABLE G43.E11

For a complete list of ICD-10 codes, please visit [cdc.gov](https://www.cdc.gov). Please contact a VYEPTI Field Access Specialist for specific questions about billing.

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ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.

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

Additional Codes That May Be Useful

Some healthcare plans may require additional documentation, and here are some additional codes that may be utilized when submitting a claim for VYEPTI. **Lundbeck recommends verifying the coding policies with your patient's healthcare plan.**

National Drug Code (NDC) for VYEPTI

An NDC is a unique, 3-segment number used as a product identifier by the US Food and Drug Administration. Some healthcare plans may require an 11-digit NDC instead of the 10-digit format. The NDC for VYEPTI is as follows.

10-Digit Format ⁷	11-Digit Format	Description
67386-130-51	67386-0130-51	CARTON CONTAINING ONE 100 MG/ML SINGLE-DOSE VIAL

Healthcare Common Procedure Coding System (HCPCS) Codes

HCPCS codes are a set of standardized codes for medical procedures, supplies, products and services that are used to process health insurance claims. The codes are established by the Centers for Medicare & Medicaid Services and divided into 2 subsystems, Level I and Level II.⁸

- Level I is comprised of CPT[®] codes, which consist of 5 characters and are used for medical services and procedures
- Level II codes are used for products, supplies, and services not covered by Level I codes. Level II codes are broken down into subsets such as J-codes and S-codes

Current Procedural Terminology[®] (CPT[®]) Codes for VYEPTI Administration

The following CPT codes may be appropriate to report intravenous (IV) administration services.

Therapeutic/Home Infusion Codes

Code ⁹	Description
96365	INTRAVENOUS INFUSION, FOR THERAPY, PROPHYLAXIS, OR DIAGNOSIS, INITIAL INFUSION, UP TO 1 HOUR
99601	HOME INFUSION SPECIALTY DRUG ADMINISTRATION, PER VISIT (UP TO 2 HOURS)

These codes require a physician or qualified healthcare professional to oversee the administration of a therapeutic.

Please contact a VYEPTI Field Access Specialist for specific questions about billing.

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For more information, please see the accompanying Full Prescribing Information and Patient Information or go to [vyepthcp.com](https://www.vyepthcp.com).



Additional Codes That May Be Useful (cont'd)

Complex Code

Complex drug infusion codes may be used for certain monoclonal antibody agents when the medical record documentation substantiates that the healthcare provider work required for the service was over and above that required for typical therapeutic agents.¹⁰

Code ¹¹	Description
96413	CHEMOTHERAPY ADMINISTRATION, INTRAVENOUS INFUSION TECHNIQUE; UP TO 1 HOUR, SINGLE OR INITIAL

Note: The term “chemotherapy” in the descriptors for CPT code 96413, in certain circumstances, applies to infusions for drugs that are not chemotherapy agents.

J-Code for VYEPTI Administration

J-codes typically include drugs that cannot be administered orally, are medically necessary for the treatment of an injury or illness, and may cover the supply, injection, or infusion of a drug or biologic.¹² The J-code to identify VYEPTI injection is shown below.

Code ⁷	Description
J3032 INJECTION	EPTINEZUMAB-JJMR, 1 MG

S-Codes for VYEPTI Administration

S-codes were developed for commercial payers to report drugs, services, and supplies.¹²

Codes ⁷	Description
S9379	HOME INFUSION THERAPY, INFUSION THERAPY, NOT OTHERWISE CLASSIFIED; ADMINISTRATIVE SERVICES, PROFESSIONAL PHARMACY SERVICES, CARE COORDINATION, AND ALL NECESSARY SUPPLIES AND EQUIPMENT (DRUGS AND NURSING VISITS CODED SEPARATELY), PER DIEM
S9810	HOME THERAPY; PROFESSIONAL PHARMACY SERVICES FOR PROVISION OF INFUSION, SPECIALTY DRUG ADMINISTRATION, AND/OR DISEASE STATE MANAGEMENT, NOT OTHERWISE CLASSIFIED, PER HOUR (DO NOT USE THIS CODE WITH ANY PER DIEM CODE)

Revenue Codes for Hospital Outpatient Departments (HOPD only)

Code ¹³	Description
0636	DRUGS REQUIRING DETAILED CODING
0260	IV THERAPY – GENERAL CLASSIFICATION

Please contact a VYEPTI Field Access Specialist for specific questions about billing.

This information is for reference only and is not intended to serve as reimbursement or legal advice, a guarantee of coverage, or a guarantee of payment for VYEPTI. Coding is a clinical decision, and all coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement.

CPT®, Current Procedural Terminology.

For more information, please see the accompanying Full Prescribing Information and Patient Information or go to [vyepthcp.com](https://www.vyepthcp.com).



Sample Claim Form CMS 1500 (Provider's Office, Home Infusion, and Non-Hospital Outpatient)

Below is a sample form CMS 1500 with information on submitting claims for VYEPTI.

BOX 21: Diagnosis or Nature of Illness or Injury
Record the appropriate ICD-10-CM diagnosis code from the patient's medical record

BOX 24A: National Drug Code
If line item NDC information is required, enter it in the shaded area of Box 24A

BOX 19: Additional Claims Information
If line item additional claims information is required, record the appropriate information
For VYEPTI CONNECT® Copay Assistance Claims: Please add VYEPTI OR J3032

BOX 24D: Procedures, Services, or Supplies
Enter the appropriate CPT code, example: VYEPTI J3032, CPT® codes, and code modifiers for VYEPTI as specified by the payer

BOX 24E: Diagnosis Pointer Record the diagnosis code number from Box 21 that applies to the procedure code indicated in Box 24D

BOX 24G: Days or Units Ensure that you are billing the correct number of units administered. Example: 100 units for 100 mg

The image shows a sample CMS 1500 Health Insurance Claim Form. Key features include:

- Header:** HEALTH INSURANCE CLAIM FORM, APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12.
- Annotations:**
 - BOX 21:** Points to the '21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY' field.
 - BOX 24A:** Points to the '24. A. DATE(S) OF SERVICE' field.
 - BOX 19:** Points to the '19. ADDITIONAL CLAIM INFORMATION' field.
 - BOX 24D:** Points to the '24. D. PROCEDURES, SERVICES, OR SUPPLIES' field.
 - BOX 24E:** Points to the '24. E. DIAGNOSIS POINTER' field.
 - BOX 24G:** Points to the '24. G. DAYS OR UNITS' field.
- Form Structure:**
 - Section 1:** PAYER INFORMATION (1. MEDICARE, 2. MEDICAID, 3. TRICARE, 4. CHAMPVA, 5. GROUP HEALTH PLAN, 6. FECA, 7. OTHER).
 - Section 2:** PATIENT INFORMATION (2. PATIENT'S NAME, 3. PATIENT'S BIRTH DATE, 4. INSURED'S NAME, 5. PATIENT'S ADDRESS, 6. PATIENT RELATIONSHIP TO INSURED, 7. INSURED'S ADDRESS, 8. RESERVED FOR NUCC USE).
 - Section 3:** INSURED'S INFORMATION (9. OTHER INSURED'S NAME, 10. IS PATIENT'S CONDITION RELATED TO:, 11. INSURED'S POLICY GROUP OR FECA NUMBER, 12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE, 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE).
 - Section 4:** ADDITIONAL INFORMATION (14. DATE OF CURRENT ILLNESS, 15. OTHER DATE, 16. DATES PATIENT UNABLE TO WORK, 17. NAME OF REFERRING PROVIDER, 18. HOSPITALIZATION DATES, 19. ADDITIONAL CLAIM INFORMATION, 20. OUTSIDE LAB?, 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY, 22. RESUBMISSION CODE, 23. PRIOR AUTHORIZATION NUMBER).
 - Section 5:** PHYSICIAN OR SUPPLIER INFORMATION (24. A. DATE(S) OF SERVICE, 24. B. PLACE OF SERVICE, 24. C. EMG, 24. D. PROCEDURES, SERVICES, OR SUPPLIES, 24. E. DIAGNOSIS POINTER, 24. F. CHARGES, 24. G. DAYS OR UNITS, 24. H. EPSON, 24. I. ID. QUAL, 24. J. RENDERING PROVIDER ID. #).
 - Section 6:** SIGNATURE AND DATE (25. FEDERAL TAX I.D. NUMBER, 26. PATIENT'S ACCOUNT NO., 27. ACCEPT ASSIGNMENT?, 28. TOTAL CHARGE, 29. AMOUNT PAID, 30. Rsvd for NUCC Use, 31. SIGNATURE OF PHYSICIAN OR SUPPLIER, 32. SERVICE FACILITY LOCATION INFORMATION, 33. BILLING PROVIDER INFO & PH #).

Lundbeck cannot guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. For additional information, customers should consult with their payers for all relevant coding, reimbursement, and coverage requirements. It is the sole responsibility of the provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement. All services must be medically appropriate and properly supported in the patient medical record.

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code.

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



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Sample Claim Form CMS 1450 (Hospital Outpatient)

Below is a sample form CMS 1450 with information on submitting claims for VYEPTI for outpatient hospital settings only.

BOX 42: Revenue Codes
Record the revenue codes that correspond to the HCPCS code in Box 44

BOX 44: HCPCS/ Rate/Health Insurance Prospective Payment System Code
Indicate appropriate CPT[®] codes and modifiers as required by the payer. Example: VYEPTI J3032

BOX 46: Ensure that you are billing the correct number of units. Example: 100 units for 100 mg

BOX 47: Total Charges
Enter the total charges for entire claim

BOX 50: Payer Name
Enter the name of the healthcare plan

BOX 51: Healthcare Plan ID
Enter the healthcare plan identification number

BOX 67: Diagnosis Code
Enter the appropriate ICD-10-CM code to identify the patient's diagnosis

1		2		3a PAT. CNTRL. # b. MED. REG. # c. FED. TAX NO.		4. TYPE OF BILL	
8 PATIENT NAME		9 PATIENT ADDRESS		6. STATEMENT PERIOD FROM		7. THROUGH	
10 BIRTHDATE	11 SEX	12 DATE	13 ADMISSION DATE	14 TYPE	15 GPO	16 DHR	17 STAT
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VYEPTI CONNECT® Can Provide Consistent, Tailored Patient Support Throughout the Treatment Journey

VYEPTI CONNECT® Copay Assistance Program

The VYEPTI CONNECT® Copay Assistance Program can help eligible patients with commercial insurance save on the cost of their VYEPTI infusion.

Your patients may pay as little as \$0 for VYEPTI*

If your patient has commercial insurance, they may be eligible to pay as little as \$0 per VYEPTI infusion every 3 months.* Offer includes up to \$200 in administration out-of-pocket fees per VYEPTI treatment of 100 mg and up to 300 mg doses.

Patients are eligible to save if they:

- Are not enrolled in any state or federal healthcare programs, such as Medicaid or Medicare
- Are 17 years of age or older
- Live in the United States or Puerto Rico
- Meet all the other Program [Terms and Conditions](#)



We've made it easy to enroll in the VYEPTI CONNECT® Copay Assistance Program

Infusion provider or physician office enrolling a patient	Patient enrolling on their own
• Enroll patient online at vyeptisavings.com by clicking on the "Enroll Today" button, then select "Healthcare Professionals" • In states where privacy laws require patient signatures, patients themselves must initiate enrollment • The provider enrolling the patient should also be the one administering the infusion	• Enroll online at vyeptisavings.com by clicking on the "Enroll Today" button, then select "Patients" • Call 833-4-VYEPTI (833-489-3784), option 1, to speak with a VYEPTI CONNECT® Patient Navigator to enroll over the phone

*For eligible patients with commercial insurance. Out-of-pocket cost may vary depending on the dose, insurance coverage, and eligibility. Talk to the patient's insurance provider for specific information about prescription coverage. Offer includes 100 mg and up to 300 mg doses. Eligibility criteria and program maximums apply. This offer is NOT available for people enrolled in Medicare, Medicaid, or any other government healthcare program. Please see the full [Terms and Conditions](#).

†Healthcare professionals and Infusion providers include those who work for Infusion Locations, HCP Offices, Hospital Outpatient Centers, Home Infusion Practices, and Specialty Pharmacies.

‡Patients living in Massachusetts and Rhode Island are not eligible to use copay assistance for VYEPTI administration costs. They can only use copay assistance for out-of-pocket costs for VYEPTI.

For more information, please see the accompanying Full [Prescribing Information](#) and [Patient Information](#) or go to vyeptihcp.com.

VYEPTI CONNECT® Can Provide Consistent, Tailored Patient Support Throughout the Treatment Journey (cont'd)



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Copay claim submission

You can submit a claim on behalf of your eligible patients through the VYEPTI CONNECT® Copay Assistance Program.

- Copay claims must be submitted within 180 days of the date of service
- Up to \$200 in administration costs may be covered
- Patients may submit a claim directly via mail or fax if:
 - They already paid for their VYEPTI treatment
 - The clinic or infusion location does not accept payment directly from the VYEPTI CONNECT® Copay Assistance Program
- To start a claim, submit a copy of the [CMS Form 1500](#) or [UB-04 Claim Form](#) and a copy of the explanation of payment or explanation of benefits from the patient's insurance carrier(s)

To submit your claim:



Electronically (EDI):
Use **Payer ID 56155**
(This Payer ID is tied to Trial Card)



Fax:
866-218-3479



Mail: **VYEPTI CONNECT®,
Copay Assistance Program**
2250 Perimeter Park, Suite 300,
Morrisville, NC 27560



Select **Enroll Today** at
vyepthisavings.com and
select **Copay Claim Upload**

Copay claim payments can be made via check or electronic funds transfer (EFT).

- The VYEPTI CONNECT® Copay Assistance Program may directly reimburse the patients via check

Please see full [Terms and Conditions](#).

For more information, please see the accompanying Full [Prescribing Information](#) and [Patient Information](#) or go to vyepthhcp.com.

VYEPTI CONNECT® Can Provide Consistent, Tailored Patient Support Throughout the Treatment Journey (cont'd)

VYEPTI CONNECT®* offers tailored patient support through a dedicated Patient Navigator, who can:

- Assess affordability options including the VYEPTI CONNECT® Copay Assistance Program
- Investigate insurance benefits and share payer coverage and prior authorization requirements
- Find convenient, in-network infusion locations and send prescription as appropriate
- Connect patients to Nurse Educators to answer treatment-related questions*



Enrolling patients in VYEPTI CONNECT® is easy and can be done by prescribing offices or patients.

Complete the enrollment form

1. Have your patients complete the authorization and commercial copay section if applicable
2. Return the enrollment form by



FAX: 866-868-7071

or



MAIL: 2250 Perimeter Park,
Suite 300 Morrisville, NC 27560

Once enrolled in VYEPTI CONNECT®, a dedicated Patient Navigator will contact you and your patient regarding next steps for accessing VYEPTI.

Tips for completing the enrollment form

- ✓ Complete all required fields
- ✓ Include your patient's insurance information as well as a copy of the front and back of your patient's medical and prescription insurance cards
- ✓ Include the patient's specific VYEPTI dosage and primary diagnosis code
- ✓ If sending the patient's prescription to a specialty pharmacy or an infusion provider, make sure to complete the Rx section. Do not complete the Rx section if choosing buy-and-bill
- ✓ Include Prescriber Certification and Authorization Signature as it is mandatory
- ✓ Have your patient complete the Patient Authorization section

Note: The VYEPTI CONNECT® Copay Assistance Program is a separate enrollment, click [here](#) for more information.

VYEPTI CONNECT® support is only available to patients who enroll; support may vary based on patient eligibility. Please see full [terms and conditions](#).

The VYEPTI CONNECT® team is committed to helping patients access VYEPTI.
To speak to a VYEPTI CONNECT® Patient Navigator, please call 833-4-VYEPTI (833-489-3784),
option 1, Monday–Friday, 8 AM–8 PM (ET)

*Nurse Educators do not provide medical advice to patients.

For more information, please see the accompanying Full [Prescribing Information](#) and [Patient Information](#) or go to [vyeptihcp.com](#).

Indication and Important Safety Information

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.

Constipation with Serious Complications: Constipation with serious complications has been reported following the use of monoclonal antibody CGRP antagonists, including VYEPTI, in the postmarketing setting. There were cases with monoclonal antibody CGRP antagonists that required hospitalization, including cases where surgery was necessary. In a majority of these cases, the onset of constipation was reported after the first dose; however, patients have also presented with constipation later on in treatment. The monoclonal antibody CGRP antagonist was discontinued in many of the reported cases of constipation with serious complications.

Monitor patients treated with VYEPTI for severe constipation and manage as clinically appropriate. The concurrent use of medications that reduce gastrointestinal motility may increase the risk for more severe constipation and the potential for constipation-related complications.

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.

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.

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 ($\geq 2\%$ 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 and Patient Information or go to vyeptihcp.com.



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Information

References: **1.** Centers for Medicare & Medicaid Services. Accessed May 21, 2025. <https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/part-b-drugs> **2.** Lavanya R, et al. *J Clin Pathways*. 2025;11(1):34-38. **3.** Medicare.gov. Accessed May 21, 2025. <https://www.medicare.gov/basics/get-started-with-medicare/get-more-coverage/your-coverageoptions/compare-original-medicare-medicare-advantage> **4.** Medicare.gov. Accessed May 21, 2025. <https://www.medicare.gov/basics/get-started-with-medicare/get-more-coverage/your-coverageoptions/compare-original-medicare-medicare-advantage> **5.** Centers for Medicare & Medicaid Services. Accessed May 21, 2025. <https://www.cms.gov/medicare/coding-billing/icd-10-codes> **6.** Data on file. Lundbeck. **7.** VYEPTI [package insert]. Deerfield, IL. Lundbeck. **8.** Centers for Medicare & Medicaid Services. Accessed June 3, 2025. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system> **9.** American Academy of Professional Coders. Accessed June 3, 2025. <https://www.aapc.com/codes/code-search/> **10.** Centers for Medicare & Medicaid Services. Accessed June 3, 2025. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=53049&ver=98> **11.** American Academy of Professional Coders. Accessed June 20, 2025. <https://www.aapc.com/blog/23016-infuse-yourself-with-coding-knowledge/> **12.** American Academy of Professional Coders. Accessed June 3, 2025. <https://www.aapc.com/resources/what-is-hcpcs> **13.** Noridian Healthcare Solutions. Accessed June 3, 2025. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-code>



HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VYEPTI safely and effectively. See full prescribing information for VYEPTI.

VYEPTI® (eptinezumab-jjmr) injection, for intravenous use
Initial U.S. Approval: 2020

----- **RECENT MAJOR CHANGES** -----
Warnings and Precautions (5.2) 06/2026

----- **INDICATIONS AND USAGE** -----
VYEPTI is a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults (1)

----- **DOSAGE AND ADMINISTRATION** -----
• Must dilute before use. For intravenous infusion only (2.1, 2.2)
• Recommended dosage is 100 mg as an intravenous infusion over approximately 30 minutes every 3 months. Some patients may benefit from a dosage of 300 mg every 3 months (2.1, 2.3)
• Dilute only in 100 mL of 0.9% Sodium Chloride Injection (2.2)

----- **DOSAGE FORMS AND STRENGTHS** -----
Injection: 100 mg/mL solution in a single-dose vial (3)

FULL PRESCRIBING INFORMATION: CONTENTS*

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----- **CONTRAINDICATIONS** -----
VYEPTI is contraindicated in patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients (4)

----- **WARNINGS AND PRECAUTIONS** -----
• Hypersensitivity Reactions: If a hypersensitivity reaction occurs, consider discontinuing VYEPTI and initiate appropriate therapy (5.1)
• Constipation with Serious Complications: Serious complications of constipation may occur (5.2)
• Hypertension: New-onset or worsening of pre-existing hypertension may occur (5.3)
• Raynaud’s Phenomenon: New-onset or worsening of pre-existing Raynaud’s phenomenon may occur (5.4)

----- **ADVERSE REACTIONS** -----
The most common adverse reactions (≥2% and 2% or greater than placebo) were nasopharyngitis and hypersensitivity (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Lundbeck at 1-800-455-1141 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.
Revised: 06/2026

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
VYEPTI is indicated for the preventive treatment of migraine in adults.

2 DOSAGE AND ADMINISTRATION
2.1 Recommended Dosing
The recommended dosage is 100 mg administered by intravenous infusion every 3 months. Some patients may benefit from a dosage of 300 mg administered by intravenous infusion every 3 months.

2.2 Dilution Instructions
VYEPTI requires dilution prior to administration. Dilute only in 100 mL 0.9% Sodium Chloride Injection. The infusion bags must be made of polyvinyl chloride (PVC), polyethylene (PE), or polyolefin (PO). Use appropriate aseptic technique when preparing VYEPTI solution for intravenous infusion. VYEPTI single-dose vials contain no preservative; discard unused portion remaining in the vial.

Dilution
100 mg dose:
To prepare the solution, withdraw 1 mL of VYEPTI from a single-dose vial using a sterile needle and syringe. Inject the 1 mL content into a 100 mL bag of 0.9% Sodium Chloride Injection.

300 mg dose:
To prepare the solution, withdraw 1 mL of VYEPTI from each of 3 single-dose vials using a sterile needle and syringe. Inject the resulting 3 mL content into a 100 mL bag of 0.9% Sodium Chloride Injection.

Storage and Handling of Diluted Product
Gently invert the VYEPTI solution to mix completely. Do not shake. Following dilution, VYEPTI solution must be infused within 8 hours. During this time, VYEPTI solution should be stored at room temperature, 20°C to 25°C (68°F to 77°F). Do not freeze.

2.3 Infusion Administration Instructions
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if the liquid contains visible particulate matter or is cloudy or discolored [see *Dosage Forms and Strengths* (3)].

No other medications should be administered through the infusion set or mixed with VYEPTI. VYEPTI is for intravenous infusion only; infuse over approximately 30 minutes. Do not administer VYEPTI as an intravenous push or bolus injection. Use an intravenous infusion set with a 0.2 micron or 0.22 micron in-line or add-on sterile filter. After the infusion is complete, flush the line with 20 mL of 0.9% Sodium Chloride Injection.

3 DOSAGE FORMS AND STRENGTHS
VYEPTI is a clear to slightly opalescent, colorless to brownish-yellow solution available as follows:
• Injection: 100 mg/mL in a single-dose vial

4 CONTRAINDICATIONS
VYEPTI is contraindicated in patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients in VYEPTI. Reactions have included anaphylaxis and angioedema [see *Warnings and Precautions* (5.1)].

5 WARNINGS AND PRECAUTIONS
5.1 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 [see *Contraindications* (4) and *Patient Counseling Information* (17)].

5.2 Constipation with Serious Complications
Constipation with serious complications has been reported following the use of monoclonal antibody CGRP antagonists, including VYEPTI, in the postmarketing setting. There were cases with monoclonal antibody CGRP antagonists that required hospitalization, including cases where surgery was necessary. In a majority of these cases, the onset of constipation was reported after the first dose; however, patients have also presented with constipation later on in treatment. The monoclonal antibody CGRP antagonist was discontinued in many of the reported cases of constipation with serious complications.

Monitor patients treated with VYEPTI for severe constipation and manage as clinically appropriate. The concurrent use of medications that reduce gastrointestinal motility may increase the risk for more severe constipation and the potential for constipation-related complications.

5.3 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.

5.4 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.

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.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Hypersensitivity Reactions [see Warnings and Precautions (5.1)]
- Constipation with Serious Complications [see Warnings and Precautions (5.2)]
- Hypertension [see Warnings and Precautions (5.3)]
- Raynaud's Phenomenon [see Warnings and Precautions (5.4)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of VYEPTI was evaluated in 2076 patients with migraine who received at least one dose of VYEPTI, representing 1615 patient-years of exposure; of these, 1524 patients were exposed to 100 mg or 300 mg. Across all doses, 1872 patients were exposed for at least 6 months and 991 patients were exposed for 12 months. In the placebo-controlled clinical studies (Study 1 and Study 2) of 1372 patients, 579 patients received at least one dose of VYEPTI 100 mg, 574 patients received at least one dose of VYEPTI 300 mg, and 588 patients received placebo [see Clinical Studies (14)]. Approximately 86% were female, 89% were white, and the mean age was 40.4 years at study entry.

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

Table 1 summarizes the adverse reactions that occurred during Study 1 and Study 2.

Table 1. Adverse Reactions Occurring with an Incidence of at Least 2% for VYEPTI and at Least 2% Greater than Placebo in Studies 1 and 2

Adverse Reactions	VYEPTI 100 mg N=579 %	VYEPTI 300 mg N=574 %	Placebo N=588 %
Nasopharyngitis	6	8	6
Hypersensitivity reactions*	1	2	0

*Hypersensitivity reactions includes multiple related adverse event terms, such as hypersensitivity, pruritus, and flushing/hot flush that occurred on the day of dosing.

In Study 1 and Study 2, 1.9% of patients treated with VYEPTI discontinued treatment because of adverse reactions [see Warnings and Precautions (5.1)].

In Study 3, the safety profile observed in 480 patients who were randomized and treated (238 to VYEPTI 100 mg and 242 to placebo) was consistent with the safety profile observed in the two pivotal placebo-controlled studies with VYEPTI (Study 1 and Study 2).

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of VYEPTI. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Gastrointestinal Disorders: Constipation [see Warnings and Precautions (5.2)]
- General Disorders and Administration Site Conditions: Fatigue
- Immune System Disorders: Anaphylaxis [see Contraindications (4) and Warnings and Precautions (5.1)]
- Vascular Disorders: Hypertension [see Warnings and Precautions (5.3)], Raynaud's phenomenon [see Warnings and Precautions (5.4)]

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to VYEPTI during pregnancy. Healthcare providers are encouraged to register pregnant patients, or pregnant women may enroll themselves in the registry by calling 1-855-810-8549 or by contacting the company at www.vyeptipregnancyregistry.lundbeck.com.

Risk Summary

There are no adequate data on developmental risks associated with the use of VYEPTI in pregnant women.

No adverse developmental effects were observed following administration of eptinezumab-jjmr to pregnant animals at doses greater than those used clinically [see Data].

In the U.S. general population, the estimated background risk of major birth defects and miscarriages in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively. The estimated rate of major birth defects (2.2%-2.9%) and miscarriage (17%) among deliveries to women with migraine are similar to rates reported in women without migraine.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data have suggested that women with migraine may be at increased risk of preeclampsia and gestational hypertension during pregnancy.

Data

Animal Data

When eptinezumab-jjmr (0, 75, or 150 mg/kg) was administered weekly to female rats and rabbits by intravenous injection throughout organogenesis, no adverse effects on embryofetal development were observed. The higher dose tested (150 mg/kg) is 30 times the maximum recommended human dose (MRHD) of 300 mg, on a body weight basis (mg/kg).

When eptinezumab-jjmr (0, 75, or 150 mg/kg) was administered weekly to female rats throughout pregnancy and lactation, no adverse effects on pre- and postnatal development were observed. The higher dose tested (150 mg/kg) is 30 times the MRHD, on a mg/kg basis.

8.2 Lactation

Risk Summary

There are no data on the presence of eptinezumab-jjmr in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VYEPTI and any potential adverse effects on the breastfed infant from VYEPTI or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of VYEPTI did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

11 DESCRIPTION

Eptinezumab-jjmr is a humanized immunoglobulin G1 (IgG1) monoclonal antibody specific for calcitonin gene-related peptide (CGRP) ligand. Eptinezumab-jjmr has an approximate molecular weight of 143 kD. Eptinezumab-jjmr is produced in *Pichia pastoris* yeast cells by recombinant DNA technology.

VYEPTI (eptinezumab-jjmr) injection is a sterile, preservative-free, clear to slightly opalescent, colorless to brownish-yellow solution, for intravenous infusion. VYEPTI is supplied as a 100 mg/mL single-dose vial. Each mL contains 100 mg eptinezumab-jjmr formulated in L-histidine (1 mg), L-histidine hydrochloride monohydrate (2.8 mg), polysorbate 80 (0.15 mg), sorbitol (40.5 mg), and Water for Injection, USP, at a pH of 5.8.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Eptinezumab-jjmr is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.

12.2 Pharmacodynamics

The relationship between the pharmacodynamic activity and the mechanism(s) by which eptinezumab-jjmr exerts its clinical effects is unknown.

12.3 Pharmacokinetics

Eptinezumab-jjmr exhibits linear pharmacokinetics and exposure increases proportionally with doses from 100 mg to 300 mg after intravenous administration. Steady-state plasma concentration is attained after the first dose with a once every 3-month dosing schedule.

Distribution

The central volume of distribution (Vc) for eptinezumab-jjmr is approximately 3.7 liters.

Metabolism & Elimination

Eptinezumab-jjmr is expected to be degraded by proteolytic enzymes into small peptides and amino acids.

The apparent clearance of eptinezumab-jjmr was 0.006 L/h, and the terminal elimination half-life was approximately 27 days.

Specific Populations

A population pharmacokinetic analysis assessing the effects of age, race, sex, and body weight did not suggest any clinically significant impact of these covariates on eptinezumab exposures.

Patients with Renal or Hepatic Impairment

No dedicated studies were conducted to assess the effects of renal or hepatic impairment on the pharmacokinetics of eptinezumab-jjmr. However, hepatic or renal impairment is not expected to affect the pharmacokinetics of eptinezumab-jjmr. A population pharmacokinetic analysis of integrated data from eptinezumab-jjmr clinical studies did not reveal clinically significant impact on pharmacokinetics of patients with hepatic or renal impairment.

Drug Interaction Studies

P450 Enzymes

Eptinezumab-jjmr is not metabolized by cytochrome P450 enzymes; therefore, interactions with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely.

Sumatriptan

The co-administration of a single dose of 300 mg eptinezumab-jjmr administered as an intravenous infusion (over a period of 1 hour ± 15 min) with a single dose of 6 mg sumatriptan administered subcutaneously did not significantly influence the pharmacokinetics of eptinezumab-jjmr or sumatriptan.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of eptinezumab-jjmr.

In patients receiving VYEPTI 100 mg or 300 mg every 3 months, the incidence of anti-eptinezumab-jjmr antibody development in Study 1 (up to 56 weeks) was 20.6% (92/447), and 41.3% (38/92) of those patients developed anti- eptinezumab-jjmr neutralizing antibodies. In Study 2 (up to 32 weeks), the incidence of anti-eptinezumab-jjmr antibody development was 18.3% (129/706), and 34.9% (45/129) of those patients developed anti-eptinezumab-jjmr neutralizing antibodies. In an open-label study with 84 weeks of treatment, 18% (23/128) of patients developed anti-eptinezumab-jjmr antibodies, and 39% (9/23) of those patients developed anti-eptinezumab-jjmr neutralizing antibodies.

Although the results from both studies showed no clear evidence of an impact from development of anti-eptinezumab-jjmr antibodies, including neutralizing antibodies, on the safety and efficacy profiles of VYEPTI, the available data are too limited to make definitive conclusions.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

The carcinogenic potential of eptinezumab-jjmr has not been assessed.

Mutagenesis

Genetic toxicology studies of eptinezumab-jjmr have not been conducted.

Impairment of Fertility

When eptinezumab-jjmr (0, 75, or 150 mg/kg) was administered weekly by intravenous injection to male and female rats prior to and during mating and continuing in females to gestation day 3-4, no adverse effects on fertility were observed. The higher dose tested (150 mg/kg) is 30 times the maximum recommended human dose of 300 mg, on a body weight basis (mg/kg).

14 CLINICAL STUDIES

The efficacy of VYEPTI was evaluated in three randomized, multicenter, placebo-controlled double-blind studies that enrolled patients with episodic and chronic migraine who were eligible for preventive treatment of migraine. In Study 1, which included patients with episodic migraine, and Study 2, which included patients with chronic migraine, either 100 mg or 300 mg VYEPTI was administered by intravenous infusion every 3 months. In Study 3, 100 mg VYEPTI was administered as a single intravenous infusion to patients with episodic or chronic migraine who were eligible for preventive migraine treatment and who had a concurrent migraine.

Study 1: Episodic Migraine

Study 1 (NCT02559895) included adults with a history of episodic migraine (4 to 14 headache days per month, of which at least 4 were migraine days). A total of 665 patients were randomized to receive placebo (N=222), 100 mg VYEPTI (N=221), or 300 mg VYEPTI (N=222) every 3 months for 12 months. Patients were allowed to use concurrent acute migraine or headache medications, including migraine-specific medications (i.e., triptans, ergotamine derivatives), during the trial.

The study excluded patients with a history of cardiovascular disease (hypertension, ischemic heart disease), neurological disease, or cerebrovascular disease.

The primary efficacy endpoint was the change from baseline in mean monthly migraine days over Months 1-3. Secondary endpoints included the percentages of patients with 50% or greater, and 75% or greater reductions from baseline in monthly migraine days over Months 1-3.

Patients had a median age of 39 years (range: 18 to 71 years), 84% were female, and 84% were white. The mean migraine frequency at baseline was approximately 8.6 migraine days per month and was similar across treatment groups.

VYEPTI treatment demonstrated statistically significant improvements compared to placebo for the primary efficacy endpoint, as shown in Table 2; secondary endpoints are also summarized in Table 2.

Table 2. Efficacy Endpoint Results in Study 1

	VYEPTI 100 mg N=221	VYEPTI 300 mg N=222	Placebo N=222
Monthly Migraine Days (MMD) – Months 1-3			
Change from baseline	-3.9	-4.3	-3.2
Difference from placebo	-0.7	-1.1	
p-value	0.018	<0.001	
≥50% MMD responders – Months 1-3			
% Responders	49.8%	56.3%	37.4%
Difference from placebo	12.4%	18.9%	
p-value	0.009*	<0.001	
≥75% MMD responders – Months 1-3			
% Responders	22.2%	29.7%	16.2%
Difference from placebo	6.0%	13.5%	
p-value	NS**	<0.001	

*Nominal statistical significance
**NS = Not statistically significant

Figure 1 shows the mean change from baseline in average monthly migraine days in Study 1. Patients treated with VYEPTI at both doses had greater mean decreases from baseline in mean monthly migraine days over Months 1-3 compared to placebo-treated patients.

Figure 1. Change from Baseline in Monthly Migraine Days in Study 1

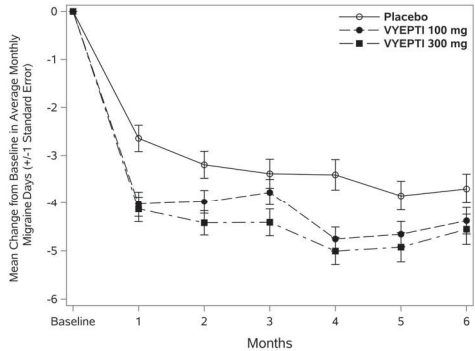


Figure 2 shows the distribution of change from baseline in mean monthly migraine days through Month 3 by treatment group in 2-day increments.

Figure 2. Distribution of Change from Baseline in Mean Monthly Migraine Days over Months 1 to 3 by Treatment Group in Study 1

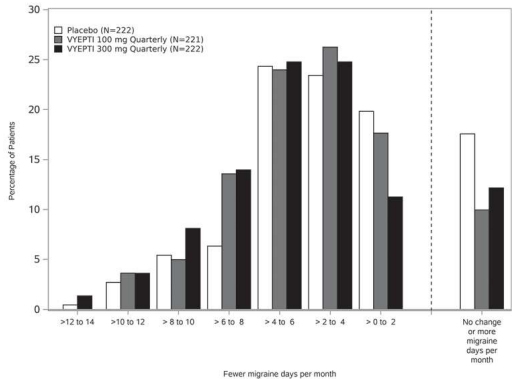
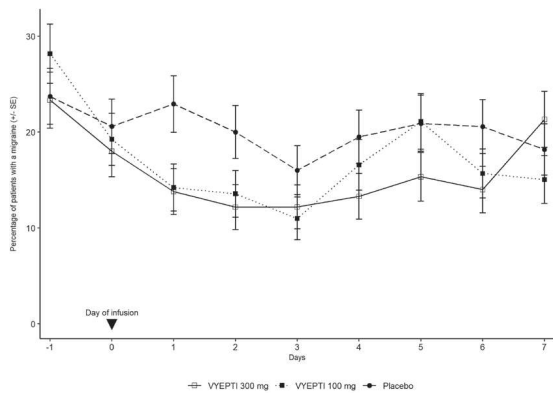


Figure 3 demonstrates that greater percentages of placebo-treated patients had migraines on most days during the first 7 days of treatment compared to VYEPTI-treated patients in Study 1.

Figure 3. Percentage of Patients with a Migraine from Day -1 (Day Prior to Infusion) to Day 7 in Study 1



Study 2: Chronic Migraine

Study 2 (NCT02974153) included adults with a history of chronic migraine (15 to 26 headache days per month, of which at least 8 were migraine days). A total of 1072 patients were randomized and received placebo (N=366), 100 mg VYEPTI (N=356), or 300 mg VYEPTI (N=350) every 3 months for 6 months. Patients were allowed to use and to continue an established stable regimen of acute migraine or headache preventive medication (except onabotulinumtoxinA). Patients with a dual diagnosis of chronic migraine and medication overuse headache attributable to acute medication overuse (triptans, ergotamine, or combination analgesics greater than 10 days per month) were included in the study population. Patients using opioids or butalbital-containing products greater than 4 days per month were not allowed.

The study excluded patients with a history of cardiovascular disease (hypertension, ischemic heart disease), neurological disease, or cerebrovascular disease.

The primary efficacy endpoint was the change from baseline in mean monthly migraine days over Months 1-3. Secondary endpoints included the percentages of patients with 50% or greater and 75% or greater reductions from baseline in monthly migraine days over Months 1-3.

Patients had a median age of 41 years (range: 18 to 65 years), 88% were female, and 91% were white. Forty-one percent of patients were taking concomitant preventive

medication for migraine. The mean migraine frequency at baseline was approximately 16.1 migraine days per month and was similar across treatment groups.

VYEPTI treatment demonstrated statistically significant improvements compared to placebo for the primary efficacy endpoint, as shown in Table 3; secondary endpoints are also summarized in Table 3.

Table 3. Efficacy Endpoint Results in Study 2

	VYEPTI 100 mg N=356	VYEPTI 300 mg N=350	Placebo N=366
Monthly Migraine Days (MMD) – Months 1-3			
Change from baseline	-7.7	-8.2	-5.6
Difference from placebo	-2.0	-2.6	
p-value	<0.001	<0.001	
≥50% MMD responders – Months 1-3			
% Responders	57.6%	61.4%	39.3%
Difference from placebo	18.2%	22.1%	
p-value	<0.001	<0.001	
≥75% MMD responders – Months 1-3			
% Responders	26.7%	33.1%	15.0%
Difference from placebo	11.7%	18.1%	
p-value	<0.001	<0.001	

Figure 4 shows the mean change from baseline in average monthly migraine days for Study 2. Patients treated with VYEPTI at both doses had greater mean decreases from baseline in mean monthly migraine days over Month 1-3 compared to placebo-treated patients.

Figure 4. Change from Baseline in Monthly Migraine Days in Study 2

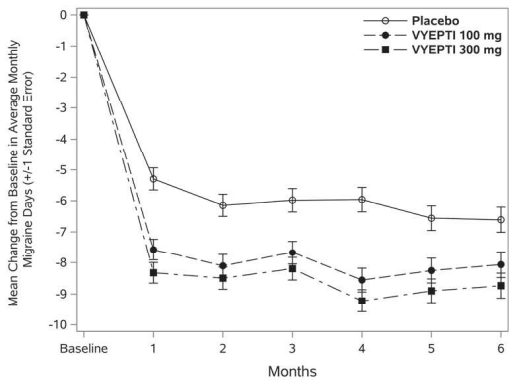


Figure 5 shows the distribution of change from baseline in mean monthly migraine days through Month 3 by treatment group in 3-day increments.

Figure 5. Distribution of Change from Baseline in Mean Monthly Migraine Days over Months 1-3 by Treatment Group in Study 2

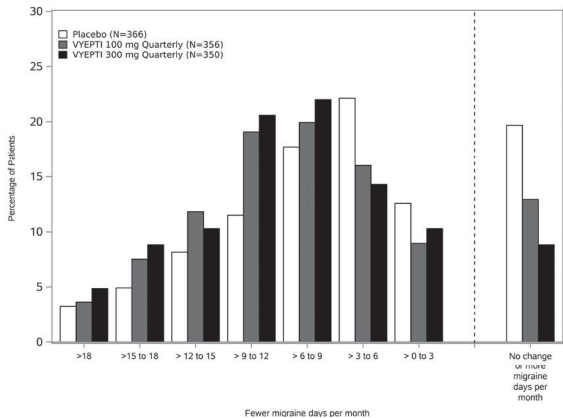
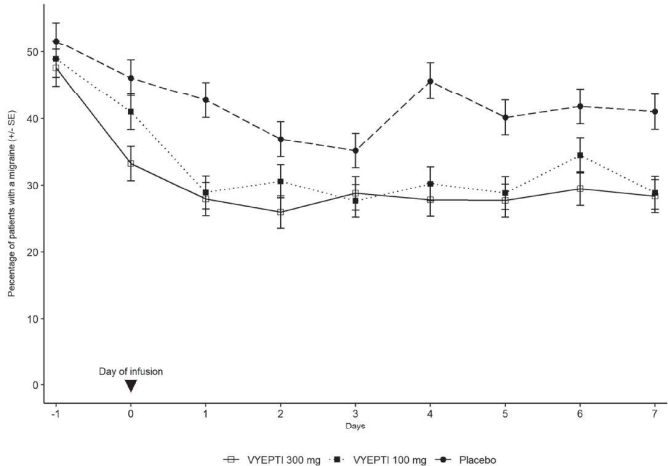


Figure 6 demonstrates that greater percentages of placebo-treated patients had migraines on individual days during the first 7 days of treatment compared to VYEPTI-treated patients in Study 2.

Figure 6. Percentage of Patients with a Migraine from Day -1 (Day Prior to Infusion) to Day 7 in Study 2



Study 3: Episodic Migraine or Chronic Migraine

Study 3 (NCT01719055) included adults who were candidates for preventive migraine therapy with VYEPTI and presented with a concurrent moderate to severe migraine on the day of infusion. A total of 480 patients were randomized to receive 100 mg VYEPTI (n=238) or placebo (n=242) as a single dose. VYEPTI demonstrated statistically significant improvements in headache pain freedom at 2 hours (VYEPTI 23.5% vs placebo 12%; p<0.001) and absence of most bothersome symptom (such as nausea, photophobia, or phonophobia) at 2 hours (VYEPTI 55.5% vs placebo 35.8%; p<0.001) as compared to placebo. The dose of 300 mg VYEPTI was not evaluated in Study 3.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

VYEPTI (eptinezumab-jjmr) injection is a clear to slightly opalescent, colorless to brownish-yellow solution supplied as:

Carton containing one 100 mg/mL single-dose vial - NDC 67386-130-51.

16.2 Storage and Handling

Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. Do not freeze or shake.

The vial stopper is not made with natural rubber latex.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Hypersensitivity Reactions

Inform patients about the signs and symptoms of hypersensitivity reactions and that these reactions can occur with VYEPTI. Advise patients to contact their healthcare provider immediately if signs or symptoms of hypersensitivity reactions occur [see Warnings and Precautions (5.1)].

Constipation with Serious Complications

Inform patients that constipation with serious complications can occur with VYEPTI. Advise patients to contact their healthcare providers if they experience severe constipation [see Warnings and Precautions (5.2)].

Hypertension

Inform patients that hypertension can develop or pre-existing hypertension can worsen with VYEPTI, and that they should contact their healthcare provider if they experience elevation in their blood pressure [see Warnings and Precautions (5.3)].

Raynaud's Phenomenon

Inform patients that Raynaud's phenomenon can develop or worsen with VYEPTI. Advise patients to discontinue VYEPTI treatment and contact their healthcare provider if they experience signs or symptoms of Raynaud's phenomenon [see Warnings and Precautions (5.4)].

Pregnancy Exposure Registry

Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to VYEPTI during pregnancy [see Use in Specific Populations (8.1)].

Lactation

Inform patients to notify their healthcare provider if they are breastfeeding or plan to breastfeed [see Use in Specific Populations (8.2)].

Manufactured by:
Lundbeck Seattle BioPharmaceuticals, Inc.
11804 North Creek Parkway South
Bothell, WA 98011 USA
U.S. License No. 2097



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EPT-L-100031

PATIENT INFORMATION

VYEPTI® (vye ep' tee)
(eptinezumab-jjmr)
injection, for intravenous use

What is VYEPTI?

VYEPTI is a prescription medicine used for the preventive treatment of migraine in adults.

It is not known if VYEPTI is safe and effective in children.

Do not receive VYEPTI if you are allergic to eptinezumab-jjmr or any of the ingredients in VYEPTI. See the end of this Patient Information leaflet for a complete list of ingredients in VYEPTI.

Before you receive VYEPTI, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure.
- have circulation problems in your fingers and toes.
- are pregnant or plan to become pregnant. It is not known if VYEPTI will harm your unborn baby.
 - **Pregnancy Registry:** There is a pregnancy registry for women who take VYEPTI. The purpose of this registry is to collect information about the health of you and your baby. You may enroll yourself by calling 1-855-810-8549 or by visiting www.vyeptipregnancyregistry.lundbeck.com. Or you may talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. It is not known if VYEPTI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using VYEPTI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive VYEPTI?

- VYEPTI will be given by a healthcare provider in a healthcare setting.
- VYEPTI is given by intravenous (IV) infusion in your vein.
- VYEPTI will be given over 30 minutes every 3 months.

If you have questions about your infusion schedule, ask your healthcare provider.

What are the possible side effects of VYEPTI?

VYEPTI may cause serious side effects, including:

- **Allergic reactions.** Allergic reactions can happen after receiving VYEPTI. Call your healthcare provider or get emergency medical help right away if you have any of the following symptoms of an allergic reaction:
 - rash
 - swelling of your face, lips, tongue or throat
 - trouble breathing
 - hives
 - redness in your face
- **Constipation with serious complications.** Severe constipation can happen after receiving VYEPTI. In some cases, people have been hospitalized. Contact your healthcare provider if you have severe constipation or constipation is associated with symptoms such as severe or constant belly pain, vomiting, swelling of belly, or bloating.
- **High blood pressure.** High blood pressure or worsening of high blood pressure can happen after receiving VYEPTI. Contact your healthcare provider if you have an increase in blood pressure.
- **Raynaud's phenomenon.** A type of circulation problem can worsen or happen after receiving VYEPTI. Raynaud's phenomenon can lead to your fingers or toes feeling numb, cool, or painful, or changing color from pale, to blue, to red. Contact your healthcare provider if these symptoms occur.

The most common side effects of VYEPTI include:

- stuffy nose and scratchy throat
- allergic reactions

These are not all of the possible side effects of VYEPTI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of VYEPTI.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet.

You can ask your pharmacist or healthcare provider for information about VYEPTI that is written for health professionals.

What are the ingredients in VYEPTI?

Active ingredient: eptinezumab-jjmr

Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sorbitol, and Water for Injection.

The vial stopper is not made with natural rubber latex.

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For more information, call 1-833-4-VYEPTI
(833-489-3784) or go to www.Vyepti.com.



This Patient Information has been approved by the U.S. Food and Drug Administration.
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