POLICY Document for VYEPTI (eptinezumab-jjmr injection, for intravenous use)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care
- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
Administration of Intravenous Vyepti

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING

This policy provides coverage for administration of Vyepti in an outpatient hospital setting for up to 90 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Vyepti in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

A. The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
B. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
C. The member has severe venous access issues that require the use of special interventions only available in the outpatient hospital setting.
D. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
E. Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
F. The member is less than 14 years of age.

For situations where administration of Vyepti does not meet the criteria for outpatient hospital infusion, coverage for Vyepti is provided when administered in alternative sites such as; physician office, home infusion.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion
B. Medical records supporting the member is medically unstable

C. Medical records supporting the member has severe venous access issues that requires specialized interventions only available in the outpatient hospital setting
D. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
E. Records supporting alternative infusion sites are greater than 30 miles from the member's home
F. Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

STEP THERAPY CRITERIA

DRUG CLASS **CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONISTS**

INJECTABLE, INTRAVENOUS INFUSION

BRAND NAME (generic)

VYEPTI
(eptinezumab-jjmr injection, for intravenous use)

Status: CVS Caremark® Criteria
Type: Initial Step Therapy with Quantity Limit;
Post Step Therapy Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Vyepti
Vyepti is indicated for the preventive treatment of migraine in adults.

INITIAL STEP THERAPY with QUANTITY LIMIT* For AIMOVIG, AJOVY, EMGALITY (except 100 mg), VYEPTI
Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 56 day supply of divalproex sodium, topiramate, valproate sodium, valproic acid, metoprolol, propranolol, timolol, atenolol, nadolol, candesartan, amitriptyline, or venlafaxine within the past 730 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.** If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

**If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

****INITIAL LIMIT QUANTITY**
Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.

Migraine:

Drug	1 Month Limit*	3 Month Limit*
Vyepti 100 mg (eptinezumab-jjmr injection, for intravenous use)	3 mL (3 single dose vials x 1 mL each) / 75 days	3 mL (3 single dose vials x 1 mL each) / 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

COVERAGE CRITERIA

Preventive Treatment of Migraine
Authorization may be granted when the requested drug is being prescribed for the preventive treatment of migraine in an adult patient when ALL of the following criteria are met:

- The request is for Aimovig, Ajovy, Emgality 120 mg, or Vyepti
- The patient has NOT received at least 3 months of treatment with the requested drug

CONTINUATION OF THERAPY

Preventive Treatment of Migraine
Authorization may be granted when the requested drug is being prescribed for the preventive treatment of migraine in an adult patient when ALL of the following criteria are met:

- The request is for Aimovig, Ajovy, Emgality 120 mg, or Vyepti
- The patient has received at least 3 months of treatment with the requested drug
- The patient had a reduction in migraine days per month from baseline

QUANTITY LIMITS APPLY

POST LIMIT QUANTITY

Migraine:

Drug	1 Month Limit*	3 Month Limit*
Vyepti 100 mg (eptinezumab-jjmr injection, for intravenous use)	3 mL (3 single dose vials x 1 mL each) / 75 days	3 mL (3 single dose vials x 1 mL each) / 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

DURATION OF APPROVAL (DOA)

- 2761-E:
  - Aimovig, Ajovy, Emgality 120 mg, Vyepti (Migraine Prevention): Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
  - Emgality 100 mg (Cluster Headache): Initial therapy DOA: 1 month; Continuation of therapy DOA: 12 months
- REG 3155-E:
  - Aimovig, Ajovy, Emgality 120 mg, Vyepti (Migraine Prevention) DOA: 12 months
  - Emgality 100 mg (Cluster Headache): Initial therapy DOA: 1 month; Continuation of therapy DOA: 12 months

REFERENCES

SECTION 1

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2. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc: October 2022.
3. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; March 2021.
4. Vyepti [package insert]. Bothell, WA: Lundbeck Seattle Bio Pharmaceuticals, Inc; October 2022.
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SECTION 2

1. Vyepti [package insert]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; October 2022.