Medical Policy:

Vyepti (eptinezumab-jjmr) intravenous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.214	January 2, 2025	June 3, 2020

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Vyepti is indicated for the preventive treatment of migraine in adults. Vyepti is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.

Length of Authorization

Coverage will be provided for 12 months and may be renewed

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 300 billable units per 84 days

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following condition:

1. **Migraine Prophylaxis**
   A. Patient is 18 years of age and older; **AND**
   B. Patient has clinically diagnosed migraine as defined as at least 8 migraine days per month (or 15 headache days) for; **AND**
   C. Patient has prior usage of at least **TWO** standard prophylactic pharmacologic therapies, each from a different pharmacologic class, used to prevent migraines or reduce migraine frequency including:
      i. Angiotensin receptor blockers;
      ii. Angiotensin Converting Enzyme Inhibitors;
      iii. Beta-blockers (i.e. propranolol, metoprolol, atenolol);
      iv. Calcium Channel blockers (i.e. verapamil);
      v. Anti-epileptics (i.e. as topiramate or divalproex sodium);
      vi. Antidepressants (venlafaxine OR a tricyclic antidepressant such as amitriptyline or nortriptyline); **AND**
   D. The patient has had inadequate efficacy to both of those standard prophylactic pharmacologic therapies, according to the prescribing physician; **OR**
   E. The patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic pharmacologic therapies, according to the prescribing physician; **OR**
   F. Patient meets **BOTH** of the following (i. and ii.):
      i. Patient has had inadequate efficacy to one standard prophylactic (preventive) pharmacologic therapy; **AND**
      ii. Patient has experienced adverse event(s) severe enough to warrant discontinuation of another standard prophylactic (preventive) pharmacologic therapy, according to the prescriber

II. RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

1. Positive response to therapy demonstrated by a 50% reduction in monthly migraine days; **AND**
2. The use of acute migraine medications (i.e. NSAIDs, triptans) has decreased since start therapy; **AND**
3. Patient has an overall improvement in function with therapy

Limitations/Exclusions

1. Concurrent use with another CGRP inhibitor
2. Vyepti is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes

Code	Description
J3032	Injection, eptinezumab-jjmr, 1 mg (Vyepti)

Applicable NDCs

Code	Description
67386-0130-51	Vyepti 100 mg/ml single-dose vial

ICD-10 Diagnoses

Code	Description
G43.019	Migraine without aura, intractable, without status migrainosus
G43.11	Migraine with aura, intractable, without status migrainosus
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.901	Migraine, unspecified, not intractable, with status migrainosus
G43.909	Migraine, unspecified, not intractable, without status migrainosus
G43.911	Migraine, unspecified, intractable, with status migrainosus
G43.919	Migraine, unspecified, intractable, without status migrainosus

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	7/8/2024	Revision: updated dosing limits
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Updated dosage limits. Initial Criteria: Removed: "Patient has prior usage in the last 18 months of at least one triptan therapy; OR Patient is intolerant to or, has a contraindication to or, inadequate response from triptan therapy**"** Added: "Patient meets **BOTH** of the following: Patient has had inadequate efficacy to one standard prophylactic (preventive) pharmacologic therapy; **AND** Patient has experienced adverse event(s) severe enough to warrant discontinuation of another standard prophylactic (preventive) pharmacologic therapy, according to the prescriber"
EmblemHealth & ConnectiCare	3/21/2023	Annual Review: Removed Patient must have tried and failed or intolerant to CGRP antagonist or inhibitor; from initial criteria
EmblemHealth & ConnectiCare	1/18/2023	Transfer to New Template
EmblemHealth & ConnectiCare	9/11/2020	Added J-Code (J3032) Injection, eptinezumab-jjmr, 1 mg (Vyepti). J-Code effective date: 10/01/2020
EmblemHealth & ConnectiCare	9/11/2020	Added C-Code (C9063) Injection, eptinezumab-jjmr, 1 mg (Vyepti). C-Code effective date: 07/01/2020
EmblemHealth & ConnectiCare	6/3/2020	New Policy

References

1. VYEPTI (eptinezumab-jjmr) [Prescribing Information] Bothell, WA: Lundbeck Seattle Biopharmaceuticals, Inc.; Feb 2020. Accessed May 15, 2020.