SmartHealth Ascension

Eptinezumab-jjmr

(Vyepti®) J3032 (1mg)

Covered with prior authorization

Eptinezumab-jjmr (Vyepti®) may be authorized when the following criteria are met:

Migraine headache prevention

- Individuals 18 years of age or older; **AND**
- Individual has 4 or more migraine headache days per month (prior to initiating a migraine-preventative medication); **AND**
- Documentation of **ONE** of the following:
    - Individual has had an inadequate response following a minimum of 3 months trial of **TWO** different prescription migraine prevention therapies from different classes of migraine prophylaxis medications including the following:
        - Antiepileptic drugs (divalproex sodium, valproate, topiramate);
        - Antidepressants (amitriptyline, venlafaxine);
        - Beta-blockers (metoprolol,propranolol, timolol);
        - OnabotulinumtoxinA (botox) for chronic migraine; **OR**
    - Individual has a contraindication per FDA label, significant intolerance, or is not a candidate for antiepileptic drugs, antidepressants, beta-blockers, and onabotulinumtoxinA;

AND

- Documentation of **ONE** of the following:
    - Inadequate response to at least ONE of the monoclonal antibody CGRP antagonists (Aimovig®, Ajovy®, or Emgality®); **OR**
    - Significant intolerance or is not a candidate for a monoclonal antibody CGRP antagonist (Aimovig®, Ajovy® or Emgality®);

AND

- Prescribed by or in consultation with a neurologist or a prescriber who specializes in migraines; **AND**
- Dose is 100 mg intravenous infusion every 3 months **OR** 300 mg intravenous infusion every 3 months.

Migraine Headache Prevention, Concurrent Use of Eptinezumab-jjmr (Vyepti®) with OnabotulinumtoxinA (Botox®)

- Individual is 18 years of age or older; **AND**
- Documentation of **ONE** of the following:
    - Individual has had an inadequate response following a minimum of 3 month trial **TWO** different prescription migraine prevention therapies from different classes of migraine prophylaxis medications including the following:
        - Antiepileptic drugs (divalproex sodium, valproate, topiramate)

        - Antidepressants (amitriptyline, venlafaxine)
        - Beta-blockers (metoprolol,propranolol, timolol)
        - OnabotulinumtoxinA (Botox®) for chronic migraine; **OR**
    - Individual has a contraindication per FDA label, significant intolerance, or is not a candidate for antiepileptic drugs, antidepressants, beta-blockers, and onabotulinumtoxinA;

AND

- Individual is continuing to experience 4 or more migraine headache days per month after therapy with **ONE** of the following preventative treatments for chronic migraine:
    - A minimum of 3 month trial of eptinezumab-jjmr (VYEPTI®)
    - A minimum of 6 month trial (2 injection cycles) of OnabotulinumtoxinA (Botox®)

Exclusion criteria:

Requests may not be approved for the following:

- Pediatric individuals (< 18 years of age)
- Acute Treatment of Migraines
- Cluster Headache, Treatment or Prevention
- Hemiplegic Migraine, Treatment or Prevention
- Concurrent use (for example, during the same time period) of two CGRP inhibitors indicated for the preventative treatment of migraine (for example, Aimovig®, Ajovy®,Emgality®,Nurtec ODT®,Vyepti®)
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk;

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.
VYEPTI® is a calcitonin gene-related peptide antagonist indicated in adults for the treatment of:

- Preventative migraines in adults

References:

Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 3rd edition (beta version). Cephalalgia. 2013; 33:629-808.
MacGregor EA. In the clinic. Migraine. Ann Intern Med. 2017; 166(7):ITC49-ITC64. Page 9 of 9 Coverage Policy Number: IP0050
Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. Headache. 2015; 52:103-122.
American Headache Society. The American Headache Society position statement on integrating new migraine

treatments into clinical practice. Headache. 2019; 59:1-18.
Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012; 78(17):1337-1345.
Goadsby PJ, Reuter U, Hallstrom Y, et al A controlled trial of erenumab for episodic migraine. N Eng J Med. 2017; 377:2123-2132.
Dodick DW, Ashine M, Brandes JL, et al. ARISE: A Phase 3 randomized trial of erenumab for episodic migraine. Cephalalgia. 2018; 38(6):1026-1037.
Vyepti® injection for intravenous use [prescribing information]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; February 2020.
Vyepti® (eptinezumab-jjmr) label. (2020, February). Accessdata.fda.gov. Retrieved June 16, 2022 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761119s000lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
June 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
July 2022	Criteria for use summary approved by Ascension Neurology Expert Review Panel
July 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.