Reference number(s)
4388-A

Standard Medicare Part B Management Vyepti

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vyepti	eptinezumab-jjmr

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Preventive Treatment of Migraines[1,2]

Authorization of 6 months may be granted for preventive treatment of migraines for members 18 years of age or older when either of the following criteria are met:

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- Member has chronic migraine headache defined as 15 to 26 headache days per month, of which at least 8 are migraine days.
- Member has episodic migraine headaches defined as 4 to 14 headache days per month, of which at least 4 are migraine days.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Vyepti.
- Vyepti is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as a reduction in migraine days per month from baseline.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Vyepti.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- The American Headache Society Consensus Statement: Update on Integrating New Migraine Treatments into Clinical Practice

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Vyepti are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information. The number of headache days and migraine days are supported by the inclusion criteria of the clinical studies listed in the prescribing information.

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References

1. Vyepti [package insert]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; March 2025.
2. Ailani J., Burch RC, Robbins MS. The American Headache Society Consensus Statement: Update on Integrating New Migraine Treatments into Clinical Practice. Headache. 2021 Jul;61(7):1021-1039

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