

Vyepti® (eptinezumab-jjmr) (Intravenous)

Document Number: IC-0527

Last Review Date: 01/05/2023

Date of Origin: 04/01/2020

Dates Reviewed: 04/2020, 10/2020, 04/2021, 04/2022, 01/2023

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Vyepti 100 mg/mL solution single-dose vial: 1 vial per 84 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 100 billable units every 84 days

III. Initial Approval Criteria ^{1,6}

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Headache Impact Test [HIT]; monthly headache day [MHD]; Migraine Disability Assessment [MIDAS]; Migraine Physical Function Impact Diary [MPFID]); **AND**

Universal Criteria ^{1,4-9}

- Other causes of headaches have been ruled out; **AND**
- Not used in combination with prophylactic calcitonin gene-related peptide (CGRP) inhibitors (e.g., eptinezumab, erenumab, galcanezumab, fremanezumab, etc.) *[Note: This does not include CGRP inhibitors used for acute treatment (i.e., ubrogepant)]*; **AND**
- Patient is not on concurrent treatment with a botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB, etc.) *[Note: This does not apply when the botulinum toxin is used for an indication other than prevention of chronic migraines]*; **AND**
- Patient is utilizing prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, physical therapy, etc.); **AND**

Preventative Treatment of Migraines † 1-9

- Patient has a diagnosis of chronic migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for > 3 months*; **AND**
 - Patient has had at least five attacks with features consistent with migraine (with and/or without aura)§; **AND**
 - On at least 8 days per month for > 3 months:
 - Headaches have characteristics and symptoms consistent with migraine§; **OR**
 - Patient suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
 - Patient has failed at least an 8-week trial of any two oral medications for the prevention of migraines (see list of prophylactic medications below for examples ±) prior to initiation of eptinezumab; **AND**
 - Patient had an inadequate response (or unable to tolerate) a minimum trial of at least two doses of a botulinum toxin; **OR**
- Patient has a diagnosis of frequent episodic migraines defined as at least 5 headache attacks lasting 4-72 hours (when untreated or unsuccessfully treated)*; **AND**
 - Headaches have characteristics and symptoms consistent with migraine without aura§; **AND**
 - Medication overuse headache has been ruled out by trial and failure of titrating off acute migraine treatments in the past

† FDA Approved Indication; ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

± Migraine-Prophylaxis Oral Medications (list not all-inclusive) 2-4,6
• Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline, etc.) • Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol etc.) • Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (ex. lisinopril, candesartan, etc.) • Anti-epileptics (e.g., divalproex, valproate, topiramate, etc) • Calcium channels blockers (e.g., verapamil, etc.)
§ Migraine Features 4,6
<u>Migraine without aura</u> • At least five attacks have the following: ○ Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated) ○ Headache has at least two of the following characteristics: – Unilateral location – Pulsating quality – Moderate or severe pain intensity – Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); AND ○ During headache at least one of the following symptoms: – Nausea and/or vomiting – Photophobia and phonophobia
<u>Migraine with aura</u> • At least two attacks have the following: ○ One or more of the following fully reversible aura symptoms: – Visual – Sensory – Speech and/or language

- Motor
- Brainstem
- Retinal; **AND**
- At least three of the following characteristics:
 - At least one aura symptom spreads gradually over ≥ 5 minutes
 - Two or more symptoms occur in succession
 - Each individual aura symptom lasts 5 to 60 minutes
 - At least one aura symptom is unilateral
 - At least one aura symptom is positive (e.g., scintillations and pins and needles)
 - The aura is accompanied, or followed within 60 minutes, by headache

IV. Renewal Criteria ^{1,4,6}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions, etc.; **AND**
- Disease response as evidenced by the following:
 - Reduction in mean monthly headache days of $\geq 50\%$ relative to the pretreatment baseline; **OR**
 - A clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:
 - Reduction of ≥ 5 points when baseline score is 11–20 OR Reduction of $\geq 30\%$ when baseline scores > 20 in the MIDAS scores; **OR**
 - Reduction of ≥ 5 points in the MPFID score; **OR**
 - Reduction of ≥ 5 points in the HIT-6 score

V. Dosage/Administration ¹

Indication	Dose
Preventative Treatment of Migraines	The recommended dosage is 100 mg administered by intravenous infusion every 3 months.

VI. Billing Code/Availability Information

HCPCS Code:

- J3032 – Injection, eptinezumab-jjmr, 1 mg: 1 billable unit = 1 mg

NDC:

- Vyepti 100 mg/mL solution for injection; single-dose vial: 67386-0130-xx

VII. References

1. Vyepti [package insert]. Bothell, WA; Lundbeck Seattle BioPharm., Inc; October 2022. Accessed December 2022.

2. Modi S, Lowder DM. Medications for migraine prophylaxis. *Am Fam Physician*. 2006 Jan 1; 73(1):72-8.
3. Pringheim T, Davenport W, Mackie G, et al. Canadian Headache Society guideline for migraine prophylaxis. *Can J Neurol Sci*. 2012 Mar; 39(2 Suppl 2):S1-S9.
4. The International Classification of Headache Disorders, 3rd edition. Headache Classification Committee of the International Headache Society (IHS) Cephalalgia. 2018; 38(1):1-211.
5. Garza I, Schwedt TJ. (2022) Chronic Migraine. In Swanson JW (Ed). *UpToDate*. Last updated: November 28, 2022. Accessed on December 1, 2022. Available from https://www.uptodate.com/contents/chronic-migraine?search=chronic%20migraine&source=search_result&selectedTitle=1~67&usage_type=default&display_rank=1
6. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. *Headache*. 2019 Jan;59(1):1-18. doi: 10.1111/head.13456. Epub 2018 Dec 10.
7. Ashina M, Saper J, Cady R, et al. Eptinezumab in episodic migraine: A randomized, double-blind, placebo-controlled study (PROMISE-1). *Cephalalgia*. 2020 Feb 19;333102420905132. doi: 10.1177/0333102420905132. [Epub ahead of print]
8. Cady R, McGill L, Hirman J, et al. Patient Global Impression of Change Related to Improvement in Most Bothersome Symptom Following Treatment With Eptinezumab (S38.009). *Neurology* Apr 2019, 92 (15 Supplement) S38.009;
9. Kudrow D, Lipton R, Silberstein S, et al. Eptinezumab for Prevention of Chronic Migraine: Results of 2 Infusions in the Phase 3 PROMISE-2 (Prevention of Migraine via Intravenous Eptinezumab Safety and Efficacy-2) Trial (P2.10-006). *Neurology* Apr 2019, 92 (15 Supplement) P2.10-006;

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G43.001	Migraine without aura, not intractable, with status migrainosus
G43.009	Migraine without aura, not intractable, without status migrainosus
G43.011	Migraine without aura, intractable, with status migrainosus
G43.019	Migraine without aura, intractable, without status migrainosus
G43.101	Migraine with aura, not intractable, with status migrainosus
G43.109	Migraine with aura, not intractable, without status migrainosus
G43.111	Migraine with aura, intractable, with status migrainosus
G43.119	Migraine with aura, intractable, without status migrainosus
G43.401	Hemiplegic migraine, not intractable, with status migrainosus
G43.409	Hemiplegic migraine, not intractable, without status migrainosus
G43.411	Hemiplegic migraine, intractable, with status migrainosus
G43.419	Hemiplegic migraine, intractable, without status migrainosus
G43.501	Persistent migraine aura without cerebral infarction, not intractable, with status migrainosus

VYEPTI® (eptinezumab-jjmr) Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

ICD-10	ICD-10 Description
G43.509	Persistent migraine aura without cerebral infarction, not intractable, without status migrainosus
G43.511	Persistent migraine aura without cerebral infarction, intractable, with status migrainosus
G43.519	Persistent migraine aura without cerebral infarction, 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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/ LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

If you believe that we have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, you can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

Traditional Chinese: 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY: 711)。

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).