 Approved Revision: Do Not Implement until 8/31/21

Eptinezumab-jjmr (Vyepti®)

NDC CODE(S) 67386-0130-XX VYEPTI 100MG/ML Solution (LUNDBECK)

DESCRIPTION

Eptinezumab-jjmr is a humanized immunoglobulin G1 (IgG1) monoclonal antibody specific for calcitonin gene-related peptide (CGRP) ligand. As a CGRP antagonist, it binds to the CGRP ligand and blocks its binding to the receptor. The mechanism(s) by which eptinezumab-jjmr exerts its clinical effects as a preventive treatment of episodic and chronic migraine is unknown.

POLICY

- Eptinezumab-jjmr for the prevention of migraine headaches is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Eptinezumab-jjmr for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient must be 18 years or older; **AND**

Universal Criteria

- Other causes of headaches have been ruled out; **AND**
- Not used in combination with other calcitonin gene-related peptide (CGRP) antagonists indicated for prophylaxis (Note: use with CGRP therapies indicated for acute use is allowed.); **AND**
- Patient is not on concurrent treatment with a botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB, etc.); **AND**
- Patient will continue to utilize prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, physical therapy, etc.); **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**
- 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**

Preventative Treatment of Migraines

- Patient has a diagnosis of chronic migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for at least 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 at least 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 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

**Patients new to therapy must initiate treatment at the lower dosing regimen of the 100 mg dose before increasing to the subsequent 200 mg dose or 300 mg dose, if required.*

Migraine-Prophylaxis Oral Medications (list not all inclusive)

- 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 channel blockers (e.g., verapamil, etc)

Migraine Features

Migraine without aura

- 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

Migraine with aura

- 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 two of the following characteristics:
    - At least one aura symptom spreads gradually over ≥5 minutes, and/or two or more symptoms occur in succession
    - Each individual aura symptom lasts 5 to 60 minutes
    - At least one aura symptom is unilateral
    - The aura is accompanied, or followed within 60 minutes, by headache

RENEWAL CRITERIA

- Patient continues to meet the universal and other indication-specific relevant criteria identified in the Initial Approval Criteria; **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 ≥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 ≥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; **AND**
- Dose escalation* (up to the maximum dose and frequency specified below) may occur upon clinical review on a case by case basis provided that the patient has:
  - Shown an initial improvement or response to therapy, as described above; **AND**
  - Had subsequent loss of response or no net decrease in frequency of headaches; **AND**
  - Received a minimum of two doses at the next stepped dose and interval specified below

**Note: Patient must have a trial of 200 mg prior to escalating to the maximum dose of 300 mg*

DOSAGE/ADMINISTRATION

INDICATION	DOSE
Migraine-Preventative Treatment	The recommended dosage is 100 mg administered by intravenous infusion every 3 months. • Some patients may benefit from a dosage of up to 300 mg every 3 months. ○ When up-dosing is deemed medically necessary, the patient must have a trial of 200 mg dosing, and be re-evaluated per the above response criteria, prior to a step-wise increase up to the maximum dosing of 300 mg.

LENGTH OF AUTHORIZATION

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

DOSING LIMITS

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

- 300 billable units every 84 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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EFFECTIVE DATE 8/31/2021

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