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5.70.081

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	May 29, 2020
Subject:	Migraine CGRP Antagonists IV	**Page:**	1 of 7

Last Review Date: December 8, 2023

Migraine Calcitonin Gene-Related Peptide (CGRP) Antagonists IV

Description

Vyepti (eptinezumab-jjmr)

Background
Vyepti is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that has high affinity for binding to the calcitonin gene-related peptide (CGRP) receptor and acts by antagonizing this receptor. Vyepti is indicated for the preventive treatment of migraine in adults. Other migraine prophylaxis options include antiepileptic drugs, antidepressants, and antihypertensive agents (1-2).

Regulatory Status
FDA-approved indication: Vyepti is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of migraine in adults (1).

The American Academy of Neurology and the American Headache Society Position Statement recommends giving at least 2 conventional oral migraine preventive treatments an adequate trial of at least 6 weeks at a target or usual effective dose prior to initiating preventive therapy with a CGRP medication (3).

The safety and effectiveness of Vyepti in pediatric patients have not been established (1).

Related policies

5-HT1 Agonists, Butalbital analgesics, Dihydroergotamine Nasal Sprays, Elyxyb, Maxalt, Migraine CGRP Antagonists Nasal, Migraine CGRP Antagonists Oral, Migraine CGRP Antagonists SC, Migraine Powders

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

CGRP antagonists IV may be considered **medically necessary** if the conditions indicated below are met.

CGRP antagonists IV may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Migraine

AND ALL of the following:

1. Used for the prevention of migraines
2. Patient has **ONE** of the following:
    a. Patient has taken a preventative CGRP medication in the past or is switching from another preventative CGRP medication
    b. Patient has had an inadequate treatment response, intolerance, or contraindication to at least **TWO** of the following prophylactic agents:
        i. Divalproex sodium/valproate sodium (Depakote, Depakote ER)
        ii. Topiramate (Topamax)
        iii. Tricyclic antidepressants: amitriptyline (Elavil), nortriptyline (Pamelor)

iv. Serotonin-norepinephrine reuptake inhibitors: venlafaxine (Effexor XR), duloxetine (Cymbalta)
v. Beta-blockers: atenolol, metoprolol, nadolol, propranolol, timolol

c. Patient has **ONE** of the following:
i. **NO** dual therapy with another CGRP antagonist (see Appendix 1)
ii. Dual therapy with a CGRP antagonist for acute treatment of migraine if **ONE** of the following applies:
a) Patient has completed an adequate 3-month trial of at least 2 preventative CGRP antagonists (i.e., Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta and Vyepti)
b) Patient has completed an adequate 3-month trial of a preventative CGRP antagonist in combination with a triptan agent

Prior–Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Migraine

AND ALL of the following:
1. Used for prevention of migraine
2. Documented decrease in migraine days from baseline **OR** improvement in daily activities due to the reduction of debilitating migraines
3. Patient has **ONE** of the following:
   a. **NO** dual therapy with another CGRP antagonist (see Appendix 1)
   b. Dual therapy with a CGRP antagonist for acute treatment of migraine if **ONE** of the following applies:
      i. Patient has completed an adequate 3-month trial of at least 2 preventative CGRP antagonists (i.e., Aimovig, Ajovy, Nurtec ODT, Emgality, Qulipta and Vyepti)

ii. Patient has completed an adequate 3-month trial of a preventative CGRP antagonist in combination with a triptan agent

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity

Drug	Quantity
Vyepti single-dose vial 100 mg/mL	3 vials per 90 days

Duration 6 months

Prior–Approval *Renewal* Limits

Quantity

Drug	Quantity
Vyepti single-dose vial 100 mg/mL	3 vials per 90 days

Duration 12 months

Rationale

Summary

Vyepti is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that has high affinity for binding to the calcitonin gene-related peptide receptor and acts by antagonizing this receptor. It is indicated for the preventive treatment of migraine in adults. The safety and effectiveness of Vyepti in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of CGRP antagonists IV while maintaining optimal therapeutic outcomes.

References

1. Vyepti [package insert]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; October 2022.
2. Silberstein, S.D. 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 78.17 (2012): 1337–1345.
3. (2019), The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache: The Journal of Head and Face Pain, 59: 1-18. https://doi.org/10.1111/head.13456

Policy History

Date	Action
May 2020	Addition to PA
June 2020	Annual review. Revised renewal requirement to “documented decrease in migraine days from baseline OR improvement in daily activities due to the reduction of debilitating migraines” per SME
June 2021	Annual review
September 2021	Annual review
March 2022	Annual review and reference update. Per SME, removed renewal requirement of “no dual therapy with Triptan Agents at PA quantities” and removed requirement of “no dual therapy with Botox for migraine prevention”
January 2023	Removed the failure of triptans requirement and increased the failure of oral prophylaxis from 1 to 2 agents, per SME. Added nortriptyline and duloxetine to the list of t/f options per AAN/AHS guidelines. Per FEP, added initiation option for patients to have taken a preventative CGRP in the past or switching from another preventative CGRP in order to bypass the t/f of prophylactics. Changed policy number to 5.70.081
March 2023	Annual review and reference update
September 2023	Annual review

October 2023	Per FEP, revised criteria to allow dual therapy between CGRP antagonists if patient is using one preventative and one acute treatment together after an adequate trial and failure of other CGRPs and triptans either alone or in combination
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.

Appendix 1 - List of CGRP Antagonists

Generic Name	Brand Name
atogepant	Qulipta
eptinezumab-jjmr	Vyepti
erenumab-aooe	Aimovig
fremanezumab-vfrm	Ajovy
galcanezumab-gnlm	Emgality
rimegepant	Nurtec ODT
ubrogepant	Ubrelvy
zavegepant	Zavzpret