Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 218.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Vyepti (eptinezumab-jjmr)

I. Policy:
Vyepti (eptinezumab-jjmr)

II. Purpose/Objective:
To provide a policy of coverage regarding Vyepti (eptinezumab-jjmr)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Vyepti (eptinezumab-jjmr) is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Vyepti (eptinezumab-jjmr) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when ALL of the following criteria are met:

- Prescription written by or in consultation with a neurologist or headache specialist **AND**
- Medical record documentation of the patient age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria **AND**
- Medical record documentation of the number of baseline migraine or headache days per month **AND**
- Medical record documentation of the patient experiencing 4 or more migraines per month **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND**
- If the request is for Vyepti 300 mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100 mg every 3 months **AND**
- If the request is for use in combination with Botox, all of the following must be met:
    - Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one calcitonin gene-related peptide (CGRP) receptor antagonist without the concomitant use of Botox **AND**
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of calcitonin gene-related peptide (CGRP) receptor antagonist **AND**
- Medical record documentation that Vyepti will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g. Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta)

AUTHORIZATION DURATION: Initial approval will be for three (3) months and subsequent approvals will be for twelve (12) months.

Reauthorization Criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency **AND**
- If the request is for Vyepti 300 mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100 mg every 3 months **AND**
- If the request is for use in combination with Botox, all of the following must be met:
    - Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one calcitonin gene-related peptide (CGRP) receptor antagonist without the concomitant use of Botox **AND**
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of calcitonin gene-related peptide (CGRP) receptor antagonist **AND**
- Medical record documentation that Vyepti will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g. Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta)

QUANTITY LIMITS:
If request is for 100 mg every 3 months:
Initial 3 months: Facets Rx count: 100 (J3032); Darwin 1 vial per 90 days; max qty supply: 1; min day supply: 84; max day supply: 90
Subsequent 12 months: Facets Rx count: 400 (J3032); Darwin 1 vial per 90 days; max qty supply: 1; min day supply: 84; max day supply: 90

If the request is for 300 mg every 3 months:
Initial 3 months: Facets Rx count: 300 (J3032); Darwin 3 vial per 90 days; max qty supply: 1; min day supply: 84; max day supply: 90
Subsequent 12 months: Facets Rx count: 1,200 (J3032); Darwin 3 vial per 90 days; max qty supply: 1; min day supply: 84; max day supply: 90

Vyepti (eptinezumab-jjmr) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Prescription written by or in consultation with a neurologist or headache specialist **AND**
- Medical record documentation of the patient age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria **AND**
- Medical record documentation of the number of baseline migraine or headache days per month **AND**
- Medical record documentation of the patient experiencing 4 or more migraines per month **AND**
- If the request is for Vyepti 300 mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100 mg every 3 months **AND**
- If the request is for use in combination with Botox, all of the following must be met:
    - Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one calcitonin gene-related peptide (CGRP) receptor antagonist without the concomitant use of Botox **AND**
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of calcitonin gene-related peptide (CGRP) receptor antagonist **AND**
- Medical record documentation that Vyepti will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g. Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta)

AUTHORIZATION DURATION: Initial approval will be for three (3) months and subsequent approvals will be for twelve (12) months.

Reauthorization Criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency **AND**
- If the request is for Vyepti 300 mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100 mg every 3 months **AND**
- If the request is for use in combination with Botox, all of the following must be met:
    - Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one calcitonin gene-related peptide (CGRP) receptor antagonist without the concomitant use of Botox **AND**
    - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of calcitonin gene-related peptide (CGRP) receptor antagonist **AND**
- Medical record documentation that Vyepti will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g. Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta)

QUANTITY LIMITS:

If request is for 100 mg every 3 months:
Initial 3 months: Facets Rx count: 100 (J3032)
Subsequent 12 months: Facets Rx count: 400 (J3032)

If the request is for 300 mg every 3 months:
Initial 3 months: Facets Rx count: 300 (J3032)
Subsequent 12 months: Facets Rx count: 1,200 (J3032)

ICHD-III Diagnostic Criteria [4]	
Migraine without Aura:	**Migraine with Aura:**
A) At least five (5) attacks fulfilling criteria B through D below:	A) At least two (2) attacks fulfilling criteria B through C below:
B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)	B) One (1) or more of the following fully reversible aura symptoms: o Visual o Sensory o Speech and/or language o Motor o Brainstem o Retinal
C) Headache with at least two (2) of the following characteristics: o unilateral location o pulsating quality o moderate to severe pain intensity o aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)	C) At least three (3) of the following: o at least one (1) aura symptom spreads over 5 or more minutes o two (2) or more aura symptoms occur in succession o each individual aura symptom lasts 5 to 60 minutes[1] o at least one (1) aura symptom is unilateral[2] o at least one (1) aura symptom is positive[3] o the aura is accompanied, or followed within 60 minutes, by a headache
D) At least one of the following during the headache: o nausea and/or vomiting o photophobia and phonophobia	D) Not better accounted for by another ICHD-3 diagnosis
E) Not better accounted for by another ICHD-3 diagnosis	

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 7/21/20

Revised: 6/7/22 (updated CGRP list), 6/2/23 (LOB carve out, Medicaid business segment)

Reviewed: 6/7/21