STEP THERAPY CRITERIA

DRUG CLASS **CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONISTS INJECTABLE, INTRAVENOUS INFUSION**

BRAND NAME (generic)

AIMOVIG
(erenumab-aooe injection)

AJOVY
(fremanezumab-vfrm injection)

EMGALITY
(galcanezumab-gnlm injection)

VYEPTI
(eptinezumab-jjmr injection, for intravenous use)

Status: CVS Caremark Criteria
Type: Initial Step Therapy with Quantity Limit;
Post Step Therapy Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

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

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

Emgality
Migraine
Emgality is indicated for the preventive treatment of migraine in adults
Cluster Headache
Emgality is indicated for the treatment of episodic cluster headache in adults

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

INITIAL STEP THERAPY with QUANTITY LIMIT* For AIMOVIG, AJOVY, EMGALITY (except 100mg), VYEPTI
******Include Rx and OTC products unless otherwise stated.*

If the patient has filled a prescription for at least a 56 day supply of divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, or venlafaxine within the past 730 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.** If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

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**If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

INITIAL STEP THERAPY* with QUANTITY LIMIT For EMGALITY 100mg
***** *Include Rx and OTC products unless otherwise stated.*

If the patient has filled a prescription for at least a 1 day supply of sumatriptan (subcutaneous or nasal) or zolmitriptan (nasal or oral) within the past 730 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.** If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

**If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

****INITIAL LIMIT QUANTITY**
Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.

Migraine:

Drug	**1 Month Limit***	**3 Month Limit***
Aimovig 70mg (erenumab-aooe injection)	2mL (2 autoinjectors or syringes x 1mL each) / 25 days	6mL (6 autoinjectors or syringes x 1mL each) / 75 days
Aimovig 140mg (erenumab-aooe injection)	1mL (1 autoinjector or syringe x 1mL each) / 25 days	3mL (3 autoinjectors or syringes x 1mL each) / 75 days
Ajovy 225mg (fremanezumab-vfrm injection)	4.5mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days	4.5mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days
Emgality 120 mg (galcanezumab-gnlm injection)		
LOADING DOSE Loading dose quantity applies to new starts of therapy (i.e. patient has not filled a prescription for Emgality in the past 180 days).	2mL (2 syringes or pens x 1mL each) / 25 days	4mL (4 syringes or pens x 1mL each) / 75 days
MAINTENANCE DOSE Maintenance dose applies to those not new to therapy (i.e., patient has filled a prescription for Emgality in the past 180 days).	1mL (1 syringe or pens x 1mL each) / 25 days	3mL (3 syringes or pens x 1mL each) / 75 days
Vyepti 100mg (eptinezumab-jjmr injection, for intravenous use)	3mL (3 single dose vials x 1mL each) / 75 days	3mL (3 single dose vials x 1mL each) / 75 days

Cluster Headache:

Drug	**1 Month Limit***	**3 Month Limit***
Emgality 100mg (galcanezumab-gnlm injection)	3mL (3 syringes x 1mL each)/ 25 days	9mL (9 syringes x 1mL each)/ 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

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COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the preventive treatment of migraine in an adult patient
  AND
  - The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline

  OR
  - The patient experienced an inadequate treatment response with an 8-week trial of any of the following: A) Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium), B) Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol), C) Antidepressants (e.g., amitriptyline, venlafaxine)
    OR
  - The patient experienced an intolerance or has a contraindication that would prohibit an 8-week trial of any of the following: A) Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium), B) Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol), C) Antidepressants (e.g., amitriptyline, venlafaxine)

  AND
  - The requested drug will not be used concurrently with another CGRP receptor antagonist

  AND
  - The request is for Aimovig, Ajovy, Emgality 120mg, or Vyepti.

OR

- The request is for Emgality 100mg for treatment of episodic cluster headaches in an adult patient
  AND
  - The patient received at least 3 weeks treatment with the requested drug and had a reduction in weekly cluster headache attack frequency from baseline
    OR
  - The patient experienced an inadequate treatment response to any of the following: A) sumatriptan (subcutaneous or nasal), B) zolmitriptan (nasal or oral)
    OR
  - The patient experienced an intolerance or contraindication to any of the following: A) sumatriptan (subcutaneous or nasal), B) zolmitriptan (nasal or oral)

  AND
  - The requested drug will not be used concurrently with another CGRP receptor antagonist

Quantity limits apply.

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POST LIMIT QUANTITY

Migraine:

Drug	1 Month Limit*	3 Month Limit*
Aimovig 70mg (erenumab-aooe injection)	2mL (2 autoinjectors or syringes x 1mL each) / 25 days	6mL (6 autoinjectors or syringes x 1mL each) / 75 days
Aimovig 140mg (erenumab-aooe injection)	1mL (1 autoinjector or syringe x 1mL each) / 25 days	3mL (3 autoinjectors or syringes x 1mL each) / 75 days
Ajovy 225mg (fremanezumab-vfrm injection)	4.5mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days	4.5mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days
Emgality 120mg (galcanezumab-gnlm injection)	1mL (1 syringe or pen x 1mL each) / 25 days	3mL (3 syringes or pens x 1mL each) / 75 days
Vyepti 100mg (eptinezumab-jjmr injection, for intravenous use)	3mL (3 single dose vials x 1mL each) / 75 days	3mL (3 single dose vials x 1mL each) / 75 days

Cluster Headache:

Drug	1 Month Limit*	3 Month Limit*
Emgality 100mg (galcanezumab-gnlm injection)	3mL (3 syringes x 1mL each)/ 25 days	9mL (9 syringes x 1mL each)/ 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

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