

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.**

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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 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 (nasal or subcutaneous) 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 70 mg, 140 mg (erenumab-aooe injection)	1 mL (1 autoinjector x 1 mL each) / 25 days	3 mL (3 autoinjectors x 1 mL each) / 75 days
Ajovy 225 mg (fremanezumab-vfrm injection)	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days	4.5 mL (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).	2 mL (2 syringes or pens x 1 mL each) / 25 days	4 mL (4 syringes or pens x 1 mL 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).	1 mL (1 syringe or pen x 1 mL each) / 25 days	3 mL (3 syringes or pens x 1 mL each) / 75 days
Vyepti 100 mg (eptinezumab-jjmr injection, for intravenous use)	3 mL (3 single dose vials x 1 mL each) / 75 days	3 mL (3 single dose vials x 1 mL each) / 75 days
Cluster Headache:		
Drug	1 Month Limit*	3 Month Limit*
Emgality 100 mg (galcanezumab-gnlm injection)	3 mL (3 syringes x 1 mL each) / 25 days	9 mL (9 syringes x 1 mL each) / 75 days

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**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.*

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 request is for Aimovig, Ajovy, Emgality 120 mg, or Vyepti.
 - AND**
 - The requested drug will not be used concurrently with another CGRP receptor antagonist
AND
 - The patient has NOT received at least 3 months of treatment with the requested drug
AND
 - 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 to, or the patient 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)
 - OR**
 - The patient has received at least 3 months of treatment with the requested drug
AND
 - The patient had a reduction in migraine days per month from baseline
- OR**
- The request is for Emgality 100 mg for the treatment of episodic cluster headaches in an adult patient
AND
 - The requested drug will not be used concurrently with another CGRP receptor antagonist
AND
 - The patient has NOT received at least 3 weeks treatment with the requested drug
AND
 - The patient experienced an inadequate treatment response to any of the following: A) sumatriptan (nasal or subcutaneous), B) zolmitriptan (nasal or oral)
 - OR**
 - The patient experienced an intolerance to, or the patient has a contraindication to any of the following: A) sumatriptan (nasal or subcutaneous), B) zolmitriptan (nasal or oral)
 - OR**
 - The patient received at least 3 weeks treatment with the requested drug
AND
 - The patient had a reduction in weekly cluster headache attack frequency from baseline

Quantity limits apply.

POST LIMIT QUANTITY		
Migraine:		
Drug	1 Month Limit*	3 Month Limit*
Aimovig 70 mg, 140 mg (erenumab-aooe injection)	1 mL (1 autoinjector) / 25 days	3 mL (3 autoinjectors x 1 mL each) / 75 days

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Ajovy 225 mg (fremanezumab-vfrm injection)	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days
Emgality 120 mg (galcanezumab-gnlm injection)	1 mL (1 syringe or pen x 1 mL each) / 25 days	3 mL (3 syringes or pens x 1 mL each) / 75 days
Vyepti 100 mg (eptinezumab-jjmr injection, for intravenous use)	3 mL (3 single dose vials x 1 mL each) / 75 days	3 mL (3 single dose vials x 1 mL 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.		

Duration of Approval (DOA):

- 2761-E:
 - Aimovig, Ajovy, Emgality 120 mg, Vyepti (Migraine Prevention): Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
 - Emgality 100 mg (Cluster Headache): Initial therapy DOA: 1 month; Continuation of therapy DOA: 12 months
- REG 3155-E:
 - Aimovig, Ajovy, Emgality 120 mg, Vyepti (Migraine Prevention): Initial therapy DOA: 12 months; Continuation of therapy DOA: 12 months
 - Emgality 100 mg (Cluster Headache): Initial therapy DOA: 1 month; Continuation of therapy DOA: 12 months

REFERENCES

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