

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 100 mg), 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, valproic acid, metoprolol, propranolol, timolol, atenolol, nadolol, candesartan, 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

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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 100 mg

**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
<i>*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.</i>		

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COVERAGE CRITERIA

Preventive Treatment of Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of migraine in an adult patient when ALL of the following criteria are met:

- The request is for Aimovig, Ajoovy, Emgality 120 mg, or Vyepti
- The patient has NOT received at least 3 months of treatment with the requested drug

Episodic Cluster Headache

Authorization may be granted when the requested drug is being prescribed for the treatment of episodic cluster headache in an adult patient when ALL of the following criteria are met:

- The request is for Emgality 100 mg
- The patient has NOT received at least 3 weeks treatment with the requested drug
- The patient meets ONE of the following:
 - The patient experienced an inadequate treatment response to sumatriptan (nasal or subcutaneous) OR zolmitriptan (nasal or oral)
 - The patient experienced an intolerance to, or the patient has a contraindication to sumatriptan (nasal or subcutaneous) OR zolmitriptan (nasal or oral)

CONTINUATION OF THERAPY

Preventive Treatment of Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of migraine in an adult patient when ALL of the following criteria are met:

- The request is for Aimovig, Ajoovy, Emgality 120 mg, or Vyepti
- The patient has received at least 3 months of treatment with the requested drug
- The patient had a reduction in migraine days per month from baseline

Episodic Cluster Headache

Authorization may be granted when the requested drug is being prescribed for the treatment of episodic cluster headaches in an adult patient when ALL of the following criteria are met:

- The request is for Emgality 100 mg
- The patient has received at least 3 weeks of treatment with the requested drug
- 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
Ajoovy 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	2 mL (2 syringes or pens x 1 mL each) / 25 days	4 mL (4 syringes or pens x 1 mL each) / 75 days

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has not filled a prescription for Emgality in the past 180 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
*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) DOA: 12 months
 - Emgality 100 mg (Cluster Headache): Initial therapy DOA: 1 month; Continuation of therapy DOA: 12 months

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