

Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists Injectable, Intravenous

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Aimovig	erenumab-aooe
Ajovy	fremanezumab-vfrm
Emgality	galcanezumab-gnlm
Vyepti	eptinezumab-jjmr

Indications

FDA-approved Indications

Aimovig

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

Reference number(s)
2761-E, 3155-E

Ajovy

Ajovy is indicated for:

- the preventive treatment of migraine in adults.
- the preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age who weigh 45 kg or more.

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

Initial Step Therapy 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 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 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 (erenumab-aooe injection)	1 mL (1 autoinjector x 1 mL each) / 25 days	3 mL (3 autoinjectors x 1 mL each) / 75 days
Ajovy (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
Emgality 120 mg (galcanezumab-gnlm injection): 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 (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:

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.

Reference number(s)
2761-E, 3155-E

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

Episodic Migraine:

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.

Drug	1 Month Limit	3 Month Limit
Ajovy (fremanezumab-vfrm injection)	1.5 mL (1 autoinjector or syringe x 1.5 mL each) / 25 days	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days

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, Ajovy, 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).

Preventive Treatment of Episodic Migraine

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

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- The request is for Ajovy.
- The patient is 6 to 17 years of age.
- The patient weighs 45 kilograms or more.
- The patient has NOT received at least 3 months of treatment with the requested drug.

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, Ajovy, 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.

Preventive Treatment of Episodic Migraine

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

- The request is for Ajovy.
- The patient is 6 to 17 years of age.
- The patient weighs 45 kilograms or more.
- 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.

Quantity Limits Apply

Post Limit Quantity

Migraine:

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.

Drug	1 Month Limit	3 Month Limit
Aimovig (erenumab-aooe injection)	1 mL (1 autoinjector) / 25 days	3 mL (3 autoinjectors x 1 mL each) / 75 days
Ajovy (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 120mg (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
Emgality 120mg (galcanezumab-gnlm injection): 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 (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:

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.

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

Reference number(s)
2761-E, 3155-E

Episodic Migraine:

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.

Drug	1 Month Limit	3 Month Limit
Ajovy (fremanezumab-vfrm injection)	1.5 mL (1 autoinjector or syringe x 1.5 mL each) / 25 days	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days

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
 - Ajovy (Episodic Migraine Prevention): Initial therapy DOA: 3 months; 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
 - Ajovy (Episodic Migraine Prevention) DOA: 12 months

References

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4. Vyepti [package insert]. Bothell, WA: Lundbeck Seattle Bio Pharmaceuticals, Inc; March 2025.
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6. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 04/23/2025).
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Reference number(s)
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