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; ***Ref # 2761-E***
Post Step Therapy Prior Authorization with Quantity Limit ***Ref # REG 3155-E***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

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 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
**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

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)

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

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
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
**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

REFERENCES

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4. Vyepti [package insert]. Bothell, WA: Lundbeck Seattle Bio Pharmaceuticals, Inc; October 2022.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed April 11, 2024.
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13. Robbins M, et al. Treatment of Cluster Headache: The American Headache Society Evidence Based Guidelines. Headache 2016;56:1093-1106.
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Written by:	UM Development (TM)
Date written:	10/2018
Revised:	(MAC) 06/2019 (new indication for Emgality), 06/2019 (added quantity limits); (JK) 08/2019 (Created REG 3155-E for regulation about DOA), 09/2019 (Added Initial Step Quantity Limits and dosing information); (TM) 02/2020 (added Vyepti); (MAC) 04/2020 (added Ajovy autoinjector, updated document title), 06/2020 (no clinical changes), 06/2021 (updated duplication of therapy question); (TM) 05/2022 (update Aimovig QL); (KMB) 06/2023 (no clinical changes), 05/2024 (removed preventive step, added candesartan to initial step), 08/2024 (removed concurrent CGRP exclusion & added valproic acid to initial step for preventive treatment drugs)
Reviewed:	Medical Affairs (EPA) 10/2018, (CHART) 08/29/2019, (CHART) 03/12/20, (CHART) 04/30/20, (CHART) 06/25/20, (CHART) 10/8/2020, 07/01/2021, 06/30/2022, 06/01/2023, 05/30/2024, 08/29/2024
External Review:	10/2018, 10/2019, 03/2020, 06/2020 (FYI), 10/2020, 10/2021, 10/2022, 10/2023, 10/2024, 10/2024 (FYI)

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the preventive treatment of migraine in an adult patient? [If Yes, then go to 2. If No, then go to 10.]	Yes	No
2	Has the patient received at least 3 months of treatment with the requested drug? [If Yes, then go to 3. If No, then go to 6.]	Yes	No
3	Is this request for any of the following: A) Aimovig, B) Ajovy, C) Emgality 120 mg, D) Vyepti? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Has the patient had a reduction in migraine days per month from baseline? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Does the patient require MORE than the plan allowance of any of the following: A) 1 injection (70 mg or 140 mg) per month of Aimovig, B) 3 injections (225 mg each) per 3 months of Ajovy, C) 1 injection (120 mg) per month of Emgality, D) 3 single dose vials (100 mg each) for intravenous infusion per 3 months of Vyepti? [No further questions] RPH Note: If yes, then deny and enter a partial approval per Post Limit Quantity Chart.	Yes	No
6	Is this request for any of the following: A) Aimovig, B) Ajovy, C) Vyepti? [If Yes, then go to 7. If No, then go to 8.]	Yes	No

7	Does the patient require MORE than the plan allowance of any of the following: A) 1 injection (70 mg or 140 mg) per month of Aimovig, B) 3 injections (225 mg each) per 3 months of Ajovy, C) 3 single dose vials (100 mg each) for intravenous infusion per 3 months of Vyepti? [No further questions] RPH Note: If yes, then deny and enter a partial approval per Post Limit Quantity Chart.	Yes	No
8	Is this request for Emgality 120 mg? [If Yes, then go to 9. If No, then no further questions.]	Yes	No
9	Does the patient require MORE than the plan allowance of 4 injections (120 mg each) per first 3 months of Emgality (i.e., loading dose of 2 injections followed by 1 injection per month)? [No further questions] RPH Note: If yes, then deny and enter a partial approval for Emgality 120 mg: 4 mL (4 syringes or pens x 1 mL each) per 75 days*.	Yes	No
10	Is this request for Emgality 100 mg for the treatment of episodic cluster headache in an adult patient? [If Yes, then go to 11. If No, then no further questions.]	Yes	No
11	Has the patient received at least 3 weeks of treatment with the requested drug? [If Yes, then go to 12. If No, then go to 14.]	Yes	No
12	Has the patient had a reduction in weekly cluster headache attack frequency from baseline? [If Yes, then go to 13. If No, then no further questions.]	Yes	No
13	Does the patient require MORE than the plan allowance of 3 injections (100 mg each) per month of Emgality? [No further questions] RPH Note: If yes, then deny and enter a partial approval for Emgality 100 mg: 3 mL (3 syringes x 1 mL each) per 25 days* OR 9 mL (9 syringes x 1 mL each) per 75 days*	Yes	No
14	Has the patient experienced an inadequate treatment response to ANY of the following: A) sumatriptan (nasal or subcutaneous), B) zolmitriptan (nasal or oral)? [If Yes, then go to 16. If No, then go to 15.]	Yes	No
15	Has the patient experienced an intolerance to or does the patient have a contraindication to ANY of the following: A) sumatriptan (nasal or subcutaneous), B) zolmitriptan (nasal or oral)? [If Yes, then go to 16. If No, then no further questions.]	Yes	No
16	Does the patient require MORE than the plan allowance of 3 injections (100 mg each) per month of Emgality? [No further questions] RPH Note: If yes, then deny and enter a partial approval for Emgality 100 mg: 3 mL (3 syringes x 1 mL each) per 25 days*	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Go to 10	
2.	Go to 3	Go to 6	
3.	Go to 4	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use for Aimovig, Ajovy, Emgality 120 mg and Vyepti is for preventative treatment of migraine in adults. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis - Aimovig, Ajovy, Emgality 120 mg, Vyepti]
4.	Go to 5	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
5.	[Please select the appropriate denial close option. RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage]. Deny	[PA Approved for 12 months. See Post Limit Quantity Chart]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers A) 1 autoinjector per month of Aimovig 70 mg, 140 mg, B) 3 autoinjectors or syringes per 3 months of Ajovy 225 mg, C) 1 syringe or pen per month of Emgality 120 mg, or D) 3 single dose vials per 3 months of Vyepti 100 mg. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Continuation, Migraine]
6.	Go to 7	Go to 8	
7.	[Please select the appropriate denial close option. RPh Note: For the denial	[PA Approved for 3 months. See Post Limit Quantity Chart]. Approve, 3	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers A) 1 autoinjector per month of Aimovig 70 mg, 140 mg, B) 3 autoinjectors or syringes per 3 months of Ajovy 225 mg, C) 3 single dose vials per 3 months of Vyepti 100 mg. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to

	verbiage, only include the requested drug. Remove all the other drugs from the verbiage]. Deny	Months	review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Initial, Migraine - Aimovig, Ajovy, Vyepti]
8.	Go to 9	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use for Aimovig, Ajovy, Vyepti and Emgality 120 mg is for preventative treatment of migraine in adults. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis - Aimovig, Ajovy, Vyepti, Emgality 120mg]
9.	Deny	[PA Approved for 3 months. Approve Emgality 120 mg 4 mL (4 syringes or pens x 1 mL each) per 75 days*]. Approve, 3 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (4 syringes or pens per first 3 months of Emgality 120 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Initial, Migraine - Emgality]
10.	Go to 11	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for preventive treatment of migraine in an adult and treatment of cluster headaches in an adult. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis - all]
11.	Go to 12	Go to 14	
12.	Go to 13	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.

			[Short Description: Continuation: Efficacy]
13.	Deny	[PA Approved for 12 months. Approve Emgality 100 mg: 3 mL (3 syringes x 1 mL each) per 25 days* OR 9 mL (9 syringes x 1 mL each) per 75 days*]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (3 syringes per month of Emgality 100 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial - Cluster]
14.	Go to 16	Go to 15	
15.	Go to 16	Deny	Your plan only covers this drug if you have tried other drugs and they did not work well for you. We have denied your request because: A) You have not tried sumatriptan (nasal or subcutaneous) or zolmitriptan (nasal or oral), and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy - Cluster]
16.	Deny	[PA Approved for 1 month. Approve Emgality 100 mg: 3 mL (3 syringes x 1 mL each) per 25 days*]. Approve, 1 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (3 syringes per month of Emgality 100 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial - Cluster]