Calcitonin Gene-Related Peptide (CGRP) Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

The BCBS MN Step Therapy Supplement applies to this program for Medicaid.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
06-01-2024	05-01-2018

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Aimovig® (erenumab-aooe) Subcutaneous autoinjector Subcutaneous prefilled syringe	Preventive treatment of migraine in adults		1
AJOVY® (fremanezumab) Subcutaneous autoinjector Subcutaneous prefilled syringe	Preventive treatment of migraine in adults		2
Emgality® (galcanezumab-gnlm) Subcutaneous prefilled pen Subcutaneous prefilled syringe	Preventive treatment of migraine in adults Treatment of episodic cluster headache in adults		3
Nurtec ODT® (rimegepant sulfate)	Acute treatment of migraine with or without aura in adults Preventive treatment of episodic migraine in adults		19

Agent(s)	FDA Indication(s)	Notes	Ref#
Orally disintegrating tablet			
QULIPTA® (atogepant) Tablet	Preventive treatment of migraine in adults		21
UBRELVY® (ubrogepant) Tablet	Acute treatment of migraine with or without aura in adults Limitations of Use: UBRELVY is not indicated for the preventive treatment of migraine.		20
Zavzpret™ (zavegepant) Nasal spray	Acute treatment of migraine with or without aura in adults Limitations of Use: Zavpret is not indicated for the preventive treatment of migraine.		23

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Migraine and Cluster Headache Management

Migraine is a common disabling primary headache disorder with high prevalence, ranking second globally in terms of years lost to disability.(7) Typical characteristics of the headache are unilateral location, pulsating quality, moderate or severe intensity, aggravation by routine physical activity, and association with nausea and/or photophobia and phonophobia. Migraines can present with or without aura, unilateral fully reversible visual, sensory, or other central nervous system symptoms that usually develop gradually and are most-often followed by headache and associated migraine symptoms.(5)

The International Classification of Headache Disorders 3rd Edition (ICHD-3) Diagnostic Criteria:(5)

Indication	Diagnostic Criteria
Migraine without aura	A. At least five attacks fulfilling criteria B-D B. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated) C. Headache has at least TWO of the following: 1. unilateral location 2. pulsating quality 3. moderate to severe pain intensity 4. aggravation by causing avoidance of routine physical activity D. During headache at least ONE of the following: 1. nausea and/or vomiting 2. photophobia and phonophobia

	E. Not better accounted for by another ICHD-3 diagnosis
Migraine with aura	A. At least two attacks fulfilling criteria B and C B. One or more of the following fully reversible aura symptoms: 1. visual 2. sensory 3. speech and/or language 4. motor 5. brainstem 6. retinal C. At least THREE of the following: 1. at least one aura symptom spreads gradually over 5 minutes or more 2. two or more aura symptoms occur in succession 3. each individual aura symptom lasts 5-60 minutes 4. at least one aura symptom is unilateral 5. at least one aura symptom is positive 6. the aura is accompanied, or followed within 60 minutes, by headache D. Not better accounted for by another ICHD-3 diagnosis
Chronic Migraine	A. Headache (migraine-like or tension-type-like) on greater than or equal to 15 days/month for greater than 3 months AND fulfilling B and C B. Occurring in patient who has had at least 5 attacks fulfilling 1. criteria B-D for migraine without aura (noted above) and/or 2. criteria B and C for migraine with aura (noted above) C. On greater than or equal to 8 days/month for greater than 3 months, fulfilling any of the following: 1. criteria C and D for migraine without aura (noted above) 2. criteria B and C for migraine with aura (noted above) 3. believed by the patient to be migraine at onset and relieved by a triptan or ergot derivative

	D. Not better accounted for by another ICHD-3 diagnosis
Cluster Headache	A. At least 5 attacks fulfilling criteria B-D B. Severe to very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (untreated) C. At least one of the following: 1. At least one of the following signs or symptoms, ipsilateral to the headache a. conjunctival injection and/or lacrimation b. nasal congestion and/or rhinorrhea c. eyelid edema d. forehead and facial sweating e. miosis and/or ptosis 2. Sense of restlessness or agitation D. Occurring with frequency between one every other day and 8 per day E. Not better accounted for by another ICHD-3 diagnosis
Episodic Cluster Headache	A. Attacks fulfilling criteria for Cluster Headache (noted above) occurring in bouts (cluster periods) B. At least two cluster periods lasting 7 days to 1 years (untreated) and separated by pain-free remission periods of at least 3 months

The IHS notes that cluster periods usually last between 2 weeks and 3 months.(5)

Migraine prevention may be of benefit in those with the following:(7,8,22)

- Frequent or long-lasting migraine headaches (greater than 4 headaches/month or headaches lasting greater than 12 hours)
- Attacks interfere significantly with patients' daily routines despite acute treatment
- Contraindication to acute therapies
- Failure of acute therapies
- Adverse effects with acute therapies
- Risk of medication overuse headache (MOH)
- Patient preference

	The American Headache Society (AHS) and the American Academy of Neurology (AAN) suggest the following agents for the prevention of migraine:(4)
	
	• Established as effective (Level A)
	  ○ Antiepileptic drugs (AEDs)
	  ▪ Divalproex
	  ▪ Valproate
	  ▪ Topiramate
	  ○ Beta blockers
	  ▪ Metoprolol
	  ▪ Propranolol
	  ▪ Timolol
	  ○ Triptans
	  ▪ Frovatriptan for short term menstrually associated migraines (MAMs) prevention
	• Probably effective (Level B)
	  ○ Antidepressants
	  ▪ Amitriptyline
	  ▪ Venlafaxine
	  ○ Beta blockers
	  ▪ Atenolol
	  ▪ Nadolol
	  ○ Triptans
	  ▪ Naratriptan, zolmitriptan for short term MAMs prevention
	
	The 2021 American Headache Society Consensus Statement recommends the following indications for initiating treatment acute treatment with gepants and ditans agents:(22)
	
	• Prescribed by a licensed clinician
	• Patient is at least 18 years of age
	• Diagnosis of ICHD-3 migraine with aura, migraine without aura, or chronic migraine
	• Either of the following:
	  ○ Contraindication to or inability to tolerate triptans
	  ○ Inadequate response to two or more oral triptans, as determined by either of the following:
	  ▪ Validated acute treatment patient-reported outcoming questionnaire (mTOQ, Migraine-ACT, PPMQ-R, FIS, PGIC)
	  ▪ Clinician attestation
	
	Lasmiditan is a selective serotonin 5HT-1F receptor agonist that lacks vasoconstrictor activity. Lasmiditan is structurally different than triptans and therefore constitutes a new class of drugs called "ditans".(22) Ditans are selective for the 5HT-1F receptor and its mechanism of action is neuronal without evidence of vasoactive effects.(27) Triptans non-specifically bind to the 5HT-1B and 5HT-1D receptors and with varying affinity bind the 5HT-1F receptors, causing direct vascular vasoconstriction. The safety, tolerability, and efficacy of co-administering lasmiditan with a triptan or a gepant has not been assessed.(22) Patients who do not respond to initial therapy with a triptan, may benefit from a second triptan or different therapy such as use of a gepant (ubrogepant or rimegepant) or a ditan (lasmiditan).(7)
	
	The 2021 American Headache Society Consensus Statement recommends the following indications for initiating treatment with a Calcitonin Gene-Related Peptide (CGRP) agent:(22)
	
	• Prescribed by a licensed clinician
	• Patient is at least 18 years of age
	• ONE of the following:
	  ○ Diagnosis of migraine with or without aura (4-7 monthly headache days) and both of the following:

	▪ Inability to tolerate (due to side effects) or inadequate response to an 8-week trial of at least two of the following: • Topiramate • Divalproex sodium/valproate sodium • Beta blocker: metoprolol, propranolol, timolol, atenolol, nadolol • Tricyclic antidepressant: amitriptyline, nortriptyline • Serotonin-norepinephrine reuptake inhibitor: venlafaxine, duloxetine • Other Level A or B treatment according to AAN-AHS guideline ▪ At least moderate disability (Migraine Disability Assessment Questionnaire [MIDAS] greater than or equal to 11, Headache Impact Test-6 [HIT]-6 greater than 50) o Diagnosis of migraine with or without aura (8-14 monthly headache days[MHDs]) and inability to tolerate (due to side effects) or inadequate response to an 8-week trial of at least two of the following: ▪ • Topiramate • Divalproex sodium/valproate sodium • Beta blocker: metoprolol, propranolol, timolol, atenolol, nadolol • Tricyclic antidepressant: amitriptyline, nortriptyline • Serotonin-norepinephrine reuptake inhibitor: venlafaxine, duloxetine • Other Level A or B treatment according to AAN-AHS guideline o Diagnosis of chronic migraine and one of the following: ▪ Inability to tolerate (due to side effects) or inadequate response to an 8-week trial of at least two of the following: • Topiramate • Divalproex sodium/valproate sodium • Beta blocker: metoprolol, propranolol, timolol, atenolol, nadolol • Tricyclic antidepressant: amitriptyline, nortriptyline • Serotonin-norepinephrine reuptake inhibitor: venlafaxine, duloxetine • Other Level A or B treatment according to AAN-AHS guideline ▪ Inability to tolerate or inadequate response to a minimum of two quarterly injection (6 months) of onabotulinum toxin A The Medical Letter Treatment Guidelines (2023) and Institute for Clinical Systems Improvement Guideline Diagnosis and Treatment of Migraine Headache - Drugs for Migraine states that a triptan is the drug of choice for moderate to severe migraine. The short-acting oral serotonin (5-HT1B/1D) receptor agonists (triptans) sumatriptan (IMITREX, and others), almotriptan (Axert, and generics), eletriptan (RELPAX), rizatriptan (Maxalt, and generics), and zolmitriptan (Zomig, and generics) are similar in efficacy.(24,25) Onset of pain relief generally occurs 30-60 minutes after administration. The longer-acting oral triptans naratriptan (Amerge, and generics) and frovatriptan (Frova, and generics) have a slower onset of action and lower initial response rate than other triptans, but they are better tolerated. Patients with migraine who have nausea or vomiting may not be able to take an oral triptan. Intranasal triptan formulations have a more rapid onset of action than oral tablets, but their efficacy is partially dependent on GI absorption of the portion of the dose that is swallowed. Use of sumatriptan nasal powder (ONZETRA Xsail) results in a faster rise in sumatriptan plasma concentrations and higher peak concentrations than use of a similar dose of sumatriptan nasal spray, suggesting that a larger portion of the dose is absorbed intranasally with the powder. Subcutaneously administered sumatriptan

	relieves pain faster (in about 10 minutes) and more effectively than other triptan formulations, but it causes more adverse effects.(25) American Headache Society (AHS) (2015): Triptans (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan [oral, nasal spray, injectable, transcutaneous patch], zolmitriptan [oral and nasal spray]) are effective (Level A) and considered by AHS guidelines (2015) to be the gold standard for acute treatment of moderate to severe migraine headaches.(8) Dihydroergotamine is recommended for use as a second- or third-line therapy for select patients or for those with refractory migraine. Intranasal dihydroergotamine has strong evidence of effectiveness but more adverse effects than triptans because of its decreased receptor specificity.(18) An assessment of new migraine treatments by the AHS (2018; updated 2021) reaffirms previous migraine guidelines. The update lists triptans, dihydroergotamine, the oral gepants (Nurtec ODT [rimegepant] and UBRELVY [ubrogepant]), and REYVOW (lasmiditan) as effective treatment of moderate or severe acute attacks and mild to moderate attacks that respond poorly to non-specific nonsteroidal anti-inflammatory drugs (NSAIDs), non-opioid analgesics, acetaminophen, or caffeinated combinations (e.g., aspirin/acetaminophen/caffeine). The recommendation remains that prescribers must consider medication efficacy and potential medication-related adverse effects, potential adverse events, patient-specific contraindications to use with a particular medication, and drug-drug interactions when prescribing acute medications for migraine.(7,8,22) The American Academy of Neurology (AAN) 2010 Guideline: Acute and preventive pharmacologic treatment of Cluster Headache (CH) state that sumatriptan subcutaneous injection and zolmitriptan nasal spray are first line-options for acute treatment of CH.(12,24) Since the publication of the 2010 AAN review, and re-reviewed in 2016, there is no new data from randomized, double-blind, controlled trials that contribute to determining the efficacy or safety for a number of acute treatments, including specifically sumatriptan and zolmitriptan. For acute treatment, sumatriptan subcutaneous, zolmitriptan nasal spray, and high flow oxygen remain the treatments with a Level A recommendation.(26) Guidelines suggest that prophylactic therapy should be started and continued for the duration of the CH period. Prophylactic pharmacological therapy includes verapamil, corticosteroids, lithium, topiramate, melatonin, gabapentin, valproic acid, ergotamine, and capsaicin. Verapamil is commonly considered the first option for prophylactic therapy in practice.(10,11,12) Corticosteroids can be used as transitional or bridging therapy until another prophylaxis agent is established.(10) Corticosteroids may be used by some practitioners for short periods of CH.(11,12) The American Academy Neurology lists the following agents as option that maybe considered or should be advised as preventative treatments: • Civamide • Suboccipital steroid injection • Melatonin • Verapamil • Lithium The European Headache Federation and WHO consensus article (2019) states the following:(13) • Individuals with migraine headaches should always be managed in primary care with the exception being chronic migraine, which likely requires specialist management • Any headache not responding satisfactorily in primary care or chronic migraine, should be referred to a specialist • In adults and children, regular high frequency use (greater than 2 day/week) of acute medication risks the development of MOH • Treatment of episodic acute migraine headaches should be approached in a step wise manner and should treat three attacks at each step before moving to the next step if needed:

- Step 1:
  - Use non-opioid analgesics, plus an antiemetic when needed
- Step 2 for adults:
  - Use triptan products
  - Triptans should not be used regularly for 10 or more days per month to avoid the risk of MOH
  - Triptan efficacy is highly variable between individuals, so patients should try different triptans and formulations. Sumatriptan subcutaneous injection should be considered when all other triptans are ineffective.
  - When vomiting is present, zolmitriptan nasal spray or sumatriptan subcutaneous injection may be preferred
- Step 2 for children and adolescents:
  - Failure of Step 1 in children should lead to specialist referral. No specific anti-migraine drugs have shown efficacy in children under 12 years of age.
  - Failure of Step 2 in adolescents (12-17 years of age), the following have shown efficacy and are approved:
    - Sumatriptan nasal spray
    - Zolmitriptan nasal spray

- Episodic migraine prophylaxis:
  - Indication for migraine prophylaxis include:
    - Attacks cause disability on two or more days per month, and
    - Acute therapy has been optimized but does not prevent this, or is poorly tolerated, or there is a risk of over-frequent use of acute therapy, even when it is effective, and
    - Patient is willing to take daily medication
    - Failure of acute therapy is an indication for migraine prophylaxis
    - For children, frequent absence from school is an additional indication for prophylaxis
  - Migraine prophylaxis agents may take 2-3 months to show efficacy
  - Children requiring prophylactic medication should be referred to a specialist
  - Medications which are effective in adult prophylaxis of episodic migraine include:
    - Beta blockers:
      - Atenolol, bisoprolol, metoprolol, propranolol
    - Amitriptyline
    - Topiramate
    - Candesartan
    - Sodium valproate
    - Flunarizine
    - CGRP
  - Onabotulinum toxin A is not effective in episodic migraine and not recommended
  - When prophylaxis therapy fails:
    - May be due to subtherapeutic dosage or duration of therapy
    - Failure of one therapy does not predict the failure of another therapy in a different class
    - Review of the following are recommended:
      - Diagnosis
      - Adherence
      - Other medications, especially for MOH causes
    - The prophylaxis therapy should be discontinued if it fails to show clear benefit
    - If all prophylaxis therapies fail, a specialist should be referred
- Chronic migraine management:
  - Chronic migraine patients should be referred to a specialist
  - Medications with efficacy in chronic migraine include:
    - Topiramate
    - Onabotulinum A
    - CGRP

	• Cluster Headache management:
	  ○ Patients should be referred to a specialist
	  ○ Acute therapies include:
	  ▪ Triptans:
	  • Sumatriptan subcutaneous injection
	  • Sumatriptan nasal spray
	  • Zolmitriptan nasal spray
	  ▪ Oxygen
	  ○ Transition and maintenance therapies include:
	  ▪ Prednisone
	  ▪ Greater occipital nerve blockade
	  ▪ Verapamil
	  ▪ Lithium carbonate
	  ▪ Topiramate
	  ○ Neuromodulation is another treatment option
	  ○ Failure of one prophylactic therapy does not predict the failure of other therapies
	  ○ Combination prophylaxis therapy can be considered though the potential for toxicity is high
	  ○ Long-term prophylaxis therapy may need to be continued
	
	The European Headache Federation guideline states the following on combining migraine prophylaxis therapy:(14)
	
	• In episodic migraine, guidelines suggest to stop oral prophylaxis migraine agents before starting CGRPs, unless the patient previously had chronic migraine prior to prophylaxis. In such patients, the suggestion is to add CGRP to the ongoing oral prophylaxis therapy
	• In chronic migraine, guidelines suggestto add CGRP to ongoing oral prophylaxis therapy
	• In chronic migraine patients on onabotulinum A therapy and are receiving inadequate treatment response, guidelines suggestto stop onabotulinum A therapy before starting CGRPs
	• In patients with chronic migraine who are on treatment with CGRP and may benefit from additional prevention, guidelines suggest to add on oral preventative agents
	• In patients with medication overuse, guidelines suggestto use CGRPs before or after withdrawal of acute medications
	
	The clinical trials referenced in FDA labeled package inserts for the preventative CGRP agents excluded patients that had received botulinum toxin within 4 months prior to receiving the CGRP agent.(15,16,17) However the 2021 American Headache Society consensus statement states that CGRP monoclonal antibody treatment (e.g., eptinezumab-jjmr, erenumab, fremanezumab, galcanezumab) may be added to greater than or equal to one established preventative treatment, based on clinical judgement, in adults who meet the ICHD-3 criteria for the following conditions:(5,22)
	
	• Migraine with/without aura (4–7 monthly migraine days [MMDs]) with at least moderate disability (Migraine Disability Assessment greater than or equal to 11 or 6-item Headache Impact Test greater than 50) and failure of an 8-week trial of greater than or equal to 2 preventive treatments with established efficacy (e.g., topiramate, divalproex sodium, beta-blocker, tricyclic antidepressant, and others)
	• Migraine with/without aura (8–14 MMDs) and failure of an 8-week trial of greater than or equal to 2 established preventive treatments
	• Chronic migraine (greater than or equal to 15 MMDs) with any level of disability and either failure of an 8-week trial of greater than or equal to two established preventive treatments or inadequate tolerability or response to onabotulinum toxin A for two quarterly injections

Medication overuse headache (MOH)	The European Headache Federation and WHO consensus article (2019) states the following:(13) • ○ Prevention is preferred ○ The four objectives of management are: ▪ Stop the overused medication ▪ Recovery from MOH ▪ Review and reassess the underlying headache disorder ▪ Prevent relapse while allowing acceptable use of medications ○ Comorbidities may require management
Safety	Atogepant is contraindicated in patients with a history of hypersensitivity to atogepant or to any of the components of QULIPTA.(21) Erenumab-aooe is contraindicated in patients with serious hypersensitivity to erenumab-aooe or to any of the excipients.(1) Fremanezumab-vfrm is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm to any of the excipients.(2) Galcanezumab-gnlm is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm to any of the excipients.(3) Rimegepant is contraindicated in patients with a history of hypersensitivity reaction to rimegepant, Nurtec ODT, or to any of its components.(19) Ubrogepant is contraindicated in the following:(20) • Concomitant use with strong CYP3A4 inhibitors • History of serious hypersensitivity to ubrogepant or any components of UBRELVY Zavegepant is contraindicated in patients with a history of hypersensitivity reaction to zavegepant or to any of the components of Zavzpret.(23)

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POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Qulipta	atogepant tab	10 MG ; 30 MG ; 60 MG	M ; N ; O ; Y	N		
Aimovig	erenumab-aooe subcutaneous soln auto-injector	140 MG/ML ; 70 MG/ML	M ; N ; O ; Y	N		

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Ajovy	fremanezumab-vfrm subcutaneous soln auto-inj	225 MG/1.5ML	M ; N ; O ; Y	N		
Ajovy	fremanezumab-vfrm subcutaneous soln pref syr	225 MG/1.5ML	M ; N ; O ; Y	N		
Emgality	galcanezumab-gnlm subcutaneous soln auto-injector	120 MG/ML	M ; N ; O ; Y	N		
Emgality	galcanezumab-gnlm subcutaneous soln prefilled syr	100 MG/ML ; 120 MG/ML	M ; N ; O ; Y	N		
Nurtec	rimegepant sulfate tab disint	75 MG	M ; N ; O ; Y	N		
Ubrelvy	ubrogepant tab	100 MG ; 50 MG	M ; N ; O ; Y	N		
Zavzpret	zavegepant hcl nasal spray	10 MG/ACT	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Qulipta	Atogepant Tab	10 MG	30	Tablets	30	DAYS			
Qulipta	Atogepant Tab	30 MG	30	Tablets	30	DAYS			
Qulipta	Atogepant Tab	60 MG	30	Tablets	30	DAYS			
Ubrelvy	Ubrogepant Tab 100 MG	100 MG	16	Tablets	30	DAYS			
Ubrelvy	Ubrogepant Tab 50 MG	50 MG	16	Tablets	30	DAYS			
Zavzpret	zavegepant hcl nasal spray	10 MG/ACT	8	Devices	30	DAYS			
Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 140 MG/ML	140 MG/ML	1	Injection Device	28	DAYS			
Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 70 MG/ML	70 MG/ML	1	Injection Device	28	DAYS			
Emgality	Galcanezumab-gnlm Subcutaneous Soln Auto-Injector 120 MG/ML	120 MG/ML	1	Injection Device	28	DAYS			
Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 100 MG/ML	100 MG/ML	9	Syringes	180	DAYS			
Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 120 MG/ML	120 MG/ML	1	Syringe	28	DAYS			
Nurtec	Rimegepant Sulfate Tab Disint 75 MG	75 MG	16	Tablets	30	DAYS			
Ajovy	Fremanezumab-vfrm Subcutaneous Soln Auto-inj 225 MG/1.5ML	225 MG/1.5 ML	3	Injection Devices	84	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Ajovy	Fremanezumab-vfrm Subcutaneous Soln Pref Syr 225 MG/1.5ML	225 MG/1.5 ML	3	Syringes	84	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Aimovig	erenumab-aooe subcutaneous soln auto-injector	140 MG/ML ; 70 MG/ML	Medicaid
Ajovy	fremanezumab-vfrm subcutaneous soln auto-inj	225 MG/1.5ML	Medicaid
Ajovy	fremanezumab-vfrm subcutaneous soln pref syr	225 MG/1.5ML	Medicaid
Emgality	galcanezumab-gnlm subcutaneous soln auto-injector	120 MG/ML	Medicaid
Emgality	galcanezumab-gnlm subcutaneous soln prefilled syr	100 MG/ML ; 120 MG/ML	Medicaid
Nurtec	rimegepant sulfate tab disint	75 MG	Medicaid
Qulipta	atogepant tab	10 MG ; 30 MG ; 60 MG	Medicaid
Ubrelvy	ubrogepant tab	100 MG ; 50 MG	Medicaid
Zavzpret	zavegepant hcl nasal spray	10 MG/ACT	Medicaid
Qulipta	atogepant tab	10 MG ; 30 MG ; 60 MG	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Qulipta	Atogepant Tab	30 MG	Medicaid
Qulipta	Atogepant Tab	10 MG	Medicaid
Qulipta	Atogepant Tab	60 MG	Medicaid
Ubrelvy	Ubrogepant Tab 100 MG	100 MG	Medicaid
Ubrelvy	Ubrogepant Tab 50 MG	50 MG	Medicaid
Zavzpret	zavegepant hcl nasal spray	10 MG/ACT	Medicaid
Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 140 MG/ML	140 MG/ML	Medicaid
Aimovig	Erenumab-aooe Subcutaneous Soln Auto-Injector 70 MG/ML	70 MG/ML	Medicaid
Emgality	Galcanezumab-gnlm Subcutaneous Soln Auto-Injector 120 MG/ML	120 MG/ML	Medicaid
Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 100 MG/ML	100 MG/ML	Medicaid
Emgality	Galcanezumab-gnlm Subcutaneous Soln Prefilled Syr 120 MG/ML	120 MG/ML	Medicaid
Nurtec	Rimegepant Sulfate Tab Disint 75 MG	75 MG	Medicaid
Ajovy	Fremanezumab-vfrm Subcutaneous Soln Auto-inj 225 MG/1.5ML	225 MG/1.5ML	Medicaid
Ajovy	Fremanezumab-vfrm Subcutaneous Soln Pref Syr 225 MG/1.5ML	225 MG/1.5ML	Medicaid

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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Indication	PDL Preferred Agents
Acute treatment of migraine with or without aura	Ubrelvy
Preventative treatment of migraine	Ajovy, Emgality
Treatment of episodic cluster headache	Emgality

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
    A. The requested agent is being used for migraine prophylaxis AND ALL of the following:
        1. ONE of the following:
            A. The patient has at least 15 headache days per month of migraine-like or tension-like headache for a minimum of 3 months (chronic migraine) AND ALL of the following:
                1. The patient has at least 8 migraine headache days per month for a minimum of 3 months **AND**
                2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP **AND**
                3. The requested agent and strength are FDA labeled for chronic migraine prophylaxis **OR**
            B. The patient has less than 15 headache days per month (episodic migraine) AND ALL of the following:
                1. ONE of the following:
                    A. The patient has greater than 4 migraine headache days per month **OR**
                    B. The patient's migraine headaches last greater than 12 hours **OR**
                    C. The patient's migraine attacks cause significant disability or diminished quality of life despite appropriate therapy with acute agents only **OR**
                    D. The patient's medication history includes acute therapies AND ONE of the following:
                        1. The patient has had an inadequate response to acute therapy **OR**
                        2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over acute therapies **OR**
                    E. The patient has contraindications to acute therapies **OR**
                    F. The patient has serious side effects to acute therapies **OR**
                    G. The patient is at risk of medication overuse headache without preventative therapy **OR**
                    H. The patient is currently being treated with the requested agent as indicated by ALL of the following:
                        1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
                        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

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	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** I. The prescriber has provided documentation that acute therapies cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP agent **AND** 3. The requested agent and strength are FDA labeled for episodic migraine prophylaxis **AND** 2. ONE of the following: A. The patient's medication history includes at least one migraine prophylaxis class [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] AND ONE of the following: 1. The patient has had an inadequate response to at least one migraine prophylaxis class [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL migraine prophylaxis class [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] **OR** B. The patient has an intolerance or hypersensitivity to therapy with at least one migraine prophylaxis class listed above **OR** C. The patient has an FDA labeled contraindication to ALL migraine prophylaxis agents listed above **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL migraine prophylaxis classed [i.e., anticonvulsants (i.e., divalproex, valproate, topiramate), beta blockers (i.e., atenolol, metoprolol, nadolol, propranolol, timolol), antidepressants (i.e., amitriptyline, venlafaxine), candesartan] cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. Medication overuse headache has been ruled out **AND** 4. ONE of the following: A. The requested agent is a preferred agent **OR** B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following:

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	1. The patient's medication history includes TWO preferred agents AND ONE of the following: A. The patient has had an inadequate response TWO preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The requested agent is being used for the treatment of episodic cluster headache AND ALL of the following: 1. The patient has had at least 5 cluster headache attacks **AND** 2. The patient has at least two cluster period lasting 7-365 days **AND** 3. The patient's cluster periods are separated by a pain-free remission period of greater than or equal to 3 months **AND** 4. ONE of the following: A. The patient's medication history includes verapamil, melatonin, corticosteroids, topiramate, OR lithium AND ONE of the following: 1. The patient has had an inadequate response to verapamil, melatonin, corticosteroids, topiramate, OR lithium **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over verapamil, melatonin, corticosteroids, topiramate, AND lithium **OR** B. The patient has an intolerance or hypersensitivity to verapamil, melatonin, corticosteroid, topiramate, OR lithium **OR** C. The patient has an FDA labeled contraindication to verapamil, melatonin, corticosteroid, topiramate, AND lithium **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that verapamil, melatonin, corticosteroids, topiramate, AND lithium cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease

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	ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. Medication overuse headache has been ruled out **AND** 6. The requested agent and strength are FDA labeled for episodic cluster headache treatment **AND** 7. ONE of the following: A. The requested agent is a preferred agent **OR** B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following: 1. The patient's medication history includes TWO preferred agents AND ONE of the following: A. The patient has had an inadequate response TWO preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The requested agent is being used for acute migraine treatment AND ALL of the following: 1. ONE of the following: A. The patient's medication history includes at least one triptan agent AND ONE of the following: 1. The patient has had an inadequate response to at least one triptan agent **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL triptan agents **OR** B. The patient has an intolerance or hypersensitivity to a triptan agent **OR** C. The patient has an FDA labeled contraindication to ALL triptan agents **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

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	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL triptan agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, ergotamine, triptan) **AND** 3. Medication overuse headache has been ruled out **AND** 4. The requested agent and strength are FDA labeled for acute migraine treatment **AND** 5. ONE of the following: A. The requested agent is a preferred agent **OR** B. The requested agent is a nonpreferred agent OR a covered drug AND ONE of the following: 1. The patient's medication history includes TWO preferred agents AND ONE of the following: A. The patient has had an inadequate response TWO preferred agents **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL preferred agents **OR** 2. The patient has an intolerance or hypersensitivity to TWO preferred agents that is not expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to ALL preferred agents that is not expected to occur with the requested agent **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that ALL preferred agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has another FDA labeled indication for the requested agent and route of administration **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The patient does not have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia

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	Length of Approval: Cluster headache treatment - 6 months; migraine prophylaxis - 6 months; all other indications - 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been approved for the requested agent previously through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. The requested agent is being used for migraine prophylaxis AND ALL of the following: 1. The patient has had improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication) with the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another prophylactic use CGRP for the requested indication **AND** 3. ONE of the following: A. BOTH of the following: 1. The patient has at least 15 headache days per month (chronic migraine) **AND** 2. The requested agent and strength are FDA labeled for chronic migraine **OR** B. BOTH of the following: 1. The patient has less than 15 headache days per month (episodic migraine) **AND** 2. The requested agent and strength are FDA labeled for episodic migraine **OR** B. The requested agent is being used for episodic cluster headache treatment AND BOTH of the following: 1. The patient has had improvement in cluster headaches management with the requested agent **AND** 2. The requested agent and strength are FDA labeled for episodic cluster headache treatment **OR** C. The requested agent is being used for acute migraine treatment AND ALL of the following: 1. The patient has had improvement in acute migraine management with the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, ergotamine, triptan) for the requested indication **AND** 3. The requested agent and strength are FDA labeled for acute migraine treatment **AND** 2. Medication overuse headache has been ruled out **OR** B. The requested agent is being used for an indication other than migraine prophylaxis, episodic cluster headache treatment, or acute migraine treatment AND has had clinical benefit with the requested agent **AND** 3. The patient does not have any FDA labeled contraindications to the requested agent

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	Compendia Allowed: CMS Approved Compendia **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. If the requested agent is being used for treatment of acute migraine, the patient has greater than 4 migraine headaches per month AND ONE of the following: 1. The patient is currently being treated with a migraine prophylactic medication (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], onabotulinum toxin A [Botox]) **OR** 2. The patient has an intolerance or hypersensitivity to therapy with migraine prophylactic medication [i.e., anticonvulsants (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], OR onabotulinum toxin A [Botox]) **OR** 3. The patient has an FDA labeled contraindication to ALL migraine prophylactic medications [i.e., anticonvulsants (i.e., anticonvulsants [i.e., divalproex, valproate, topiramate], beta blockers [i.e., atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [i.e., amitriptyline, venlafaxine], candesartan, prophylactic use CGRP [e.g., Aimovig, AJOVY, Emgality, Nurtec, QULIPTA, Vyepti], AND onabotulinum toxin A [Botox]) **OR** 4. There is support that the patient's migraine is manageable with acute therapy alone **AND** D. There is support of therapy with a higher dose for the requested indication **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** Initial: For migraine prophylaxis: up to 6 months. NOTE: For agents that require a loading dose for a new start, approve the loading dose based on FDA labeling AND the maintenance dose for the remainder of the 6 months. For cluster headache treatment: up to 6 months

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	All other indications: up to 12 months Renewal: up to 12 months