Acute Migraine Agents Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

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

Requests for an oral liquid form of a drug must be approved if BOTH of the following apply:

1) the indication is FDA approved AND

2) the patient is using an enteral tube for feeding or medication administration

POLICY REVIEW CYCLE

Effective Date	Date of Origin
03-01-2024	09-01-2020

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Elyxyb™ (celecoxib) Oral solution	Acute treatment of migraine headaches with or without aura in adults		12
Migranal® (dihydroergotamine mesylate)* Nasal Spray	Acute treatment of migraine headaches with or without aura Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine	*generic equivalent available	1
Reyvow® (lasmitidan) Tablet	Acute treatment of migraine with or without aura in adults		2
Trudhesa™ (dihydroergotamine mesylate) Nasal aerosol	Acute treatment of migraine with or without aura in adults **Limitations of Use:** • Not indicated for the preventive treatment of migraine • Not indicated for the management of hemiplegic or basilar migraine		10

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

CLINICAL RATIONALE

Acute Migraine	Migraine is a common disabling primary headache disorder. 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.(4) The diagnostic criteria for chronic migraine require the inclusion of all of the following:(4) 1. Headache (migraine-like or tension-like) on greater than or equal to 15 days per month for greater than 3 months and fulfilling criteria B and C 2. Occurring in a patient who has had at least five attacks fulfilling migraine without aura and/or migraine with aura 3. On greater than or equal to 8 days per month for greater than 3 months, fulfilling any of the following: A. Migraine without aura B. Migraine with aura C. Believed by the patient to be migraine at onset and relieved by a triptan or ergot derivative 4. Not better accounted for by another ICHD-3 diagnosis. Migraine prevention may be of benefit in those with the following:(3,5,6) • Frequent or long-lasting migraine headaches (greater than 4 headaches/month or headaches lasting greater than 12 hours) • Migraine attacks that cause significant disability or diminished quality of life despite appropriate acute treatment • Contraindication to acute therapies • Failure of acute therapies • Serious adverse effects of acute therapies • Risk of medication overuse headache • Menstrual migraine The American Headache Society (AHS) also includes patient preference as a consideration.(7) The American Headache Society (AHS) and the American Academy of Neurology (AAN) suggest the following agents for the prevention of migraine:(3) • 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 2018 American Headache Society Consensus Statement recommends the following indications for initiating treatment with a Calcitonin Gene-Related Peptide (CGRP) agent:(6) • Prescribed by a licensed medical professional • Patient is at least 18 years of age • ONE of the following: o 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 a 6-week trial of at least 2 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 11, Headache Impact Test-6 [HIT]-6 greater than 50) o Diagnosis of migraine with or without aura (8-14 monthly headache days) and inability to tolerate (due to side effects) or inadequate response to a 6-week trial of at least 2 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 a 6-week trial of at least 2 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 2 quarterly injection (6 months) of onabotulinum toxin A Triptans (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan), are considered by American Headache Society guidelines (2015) to be the gold standard for acute treatment of moderate to severe migraine headaches.(7) 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.(11) An assessment of new migraine treatments by the American Headache society (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 nonsteroidal anti-inflammatory drugs, non-opioid analgesics, acetaminophen, or caffeinated combinations (e.g., aspirin/acetaminophen/caffeine). The recommendation also remains that prescribers must consider medication efficacy and potential medication-related adverse effects when prescribing acute medications for migraine.(6,13)
	
	Lasmiditan is a selective serotonin (5HT) 1F receptor agonist that lacks vasoconstrictor activity. Structurally different than triptans, this compound constitutes a new class of drugs, "ditans". While 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, ditans are selective for the 5HT-1F receptor and its mechanism of action is neuronal without evidence of vasoactive effects.(14) The safety, tolerability, and efficacy of co-administering lasmiditan with a triptan or a gepant has not been assessed.(13)
	
	The European Headache Federation and WHO consensus article (2019) states the following:(8)
	
	• Individuals with migraine headaches should almost always be managed in primary care. The exception being chronic migraine, which likely requires specialist management.
	• Any headache not responding satisfactorily in primary care should be referred to a specialist
	• In adults and children, regular high frequency use (greater than 2 days/week) of acute medication risks the development of medication-overuse headache
	• 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 on greater than or equal to 10 days/month to avoid the risk of medication overuse headaches
	  ▪ 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 nausea 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
	• For 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 the patient is willing to take daily medication

	▪ Failure of acute therapy is an indication for migraine prophylaxis ▪ For children: frequent absence from school o Migraine prophylaxis agents may take 2-3 months to show efficacy o Children requiring prophylactic medication should be referred to a specialist o Medications which are effective in adult prophylaxis of episodic migraine include: ▪ Beta blockers: • Atenolol, bisoprolol, metoprolol, propranolol ▪ Amitriptyline ▪ Topiramate ▪ Candesartan ▪ Sodium valproate ▪ Flunarizine ▪ CGRP o Onabotulinum toxin A is not effective in episodic migraine o When prophylaxis therapy fails: ▪ Failure may be due to subtherapeutic dosage or duration of therapy ▪ Failure of one therapy does not predict the failure of another therapy ▪ Review of the following are recommended: • Diagnosis • Adherence • Other medications, especially for medication overuse headache 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: o Chronic migraine patients should be referred to a specialist o Medications with efficacy in chronic migraine include: ▪ Topiramate ▪ Onabotulinum A ▪ CGRP The European Headache Federation guideline states the following on combining migraine prophylaxis therapy:(9) • In episodic migraine, it's suggested 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, it's suggested to add CGRP to ongoing oral prophylaxis therapy • In chronic migraine patients on onabotulinum A therapy and are receiving inadequate treatment response, it's suggested to stop onabotulinum A therapy before starting CGRPs • In patients with chronic migraine who are on treatment with CGRP and may benefit from additional prevention, it is suggested to add on oral preventative agents • In patients with medication overuse, it is suggested to use CGRPs before or after withdrawal of acute medications
Medication overuse headache (MOH)	The European Headache Federation and WHO consensus article (2019) states the following:(8) • o Prevention is preferred o 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 also require management
Safety	Elyxyb has the following boxed warnings:(12) • Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use • Elyxyb is contraindicated in the setting of coronary artery bypass graft (CABG) surgery • NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious (GI) events Elyxyb is contraindicated in the following:(12) • Patients with known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to celecoxib, any components of the drug product • Patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs • In the setting of coronary artery bypass graft (CABG) surgery • Patients who have demonstrated allergic-type reactions to sulfonamides Migranal has the following boxed warning:(1) Serious and/or life-threatening peripheral ischemia has been associated with the coadministration of dihydroergotamine with potent CYP 3A4 inhibitors including protease inhibitors and macrolide antibiotics. Because CYP 3A4 inhibition elevates the serum levels of dihydroergotamine, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Hence, concomitant use of these medications is contraindicated. Migranal is contraindicated in the following:(1) • Patients with ischemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischemia) or patients who have clinical symptoms or findings consistent with coronary artery vasospasm including Prinzmetal's variant angina • Patients with uncontrolled hypertension • Use within 24 hours of 5-HT1 agonists (e.g., sumatriptan), ergotamine-containing or ergot-type medications, or methysergide • Patients with hemiplegic or basilar migraine • Patients with known peripheral arterial disease, sepsis, following vascular surgery, and severely impaired hepatic or renal function • Pregnant women • Patients who have previously shown hypersensitivity to ergot alkaloids • Nursing mothers • Use with peripheral and central vasoconstrictors Lasmiditan has no contraindications or boxed warnings.(2)

	Trudhesa has the following boxed warning:(10) Serious and/or life-threatening peripheral ischemia has been associated with the coadministration of dihydroergotamine with strong CYP3A4 inhibitors. Because CYP3A4 inhibition elevates the serum levels of dihydroergotamine, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Hence, concomitant use of Trudhesa with strong CYP3A4 inhibitors is contraindicated. Trudhesa is contraindicated in the following:(10) • Concomitant use of strong CYP3A4 inhibitors • Patients with ischemic heart disease or coronary artery vasospasm • Patients with uncontrolled hypertension, peripheral arterial diseases, sepsis, following vascular surgery, or severe hepatic or renal impairment • Patients with hypersensitivity to ergot alkaloids • Concomitant use of other 5-HT agonists (e.g., sumatriptan) or ergotamine-containing or ergot-type medications within 24 hours • Concomitant use of peripheral and central vasoconstrictors

REFERENCES

Number	Reference
1	Migranal prescribing information. Bausch Health US, LLC. September 2022.
2	Reyvow prescribing information. Eli Lilly and Co. September 2022.
3	Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012;78(17):1337.
4	ICHD-3 Classification. International Headache Society. 2018.
5	Silberstein SD. Practice parameter: Evidence-based guidelines for migraine headache (an evidence-based review) Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. September 26, 2000; 55 (6)
6	The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. American Headache Society. 12/10/2018. Available at https://onlinelibrary.wiley.com/doi/10.1111/head.13456.
7	Marmura M, Silberstein SD, Schwedt TJ. The acute treatment of migraine in adults: the American Headache Society evidence assessment of migraine pharmacotherapies. Headache. 2015;55:3–20.
8	Steiner TJ, Jensen R, Katsarava Z, et al. Aids to management of headache disorders in primary care (2nd edition). Journal of Headache and Pain. (2019) 20:57.
9	Sacco S, Bendtsen L, Ashina M, et al. European headache federation guideline on the use of monoclonal antibodies acting on the calcitonin gene related peptide or its receptor for migraine prevention. The Journal of Headache and Pain. (2019) 20:6.
10	Trudhesa prescribing information. Impel NeuroPharma, Inc. September 2021.
11	Mayans L, Walling A. Acute Migraine Headache: Treatment Strategies. Am Fam Physician. 2018;97(4):243-251.
12	Elyxyb prescribing information. BioDelivery Sciences International Inc. April 2021.
13	Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61(7):1021-1039.
14	Oswald JC, Schuster NM. Lasmiditan for the treatment of acute migraine: a review and potential role in clinical practice. J Pain Res. 2018 Oct 8;11:2221-2227.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Elyxyb	celecoxib oral soln	120 MG/4.8ML	M ; N ; O ; Y	N		
Trudhesa	dihydroergotamine mesylate hfa nasal aerosol	0.725 MG/ACT	M ; N ; O ; Y	N		
Migranal	Dihydroergotamine Mesylate Nasal Spray 4 MG/ML	4 MG/ML	M ; N ; O ; Y	O ; Y		
Reyvow	lasmiditan succinate tab	100 MG ; 50 MG	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
Elyxyb	Celecoxib Oral Soln	120 MG/4.8 ML	6	Bottles	30	DAYS			
Migranal	Dihydroergotamine Mesylate Nasal Spray 4 MG/ML	4 MG/ML	8	mLs	28	DAYS			
Reyvow	Lasmiditan Succinate Tab 100 MG	100 MG	8	Tablets	30	DAYS			
Reyvow	Lasmiditan Succinate Tab 50 MG	50 MG	8	Tablets	30	DAYS			
Trudhesa	Dihydroergotamine Mesylate HFA Nasal Aerosol	0.725 MG/ACT	12	mLs	28	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Elyxyb	celecoxib oral soln	120 MG/4.8ML	
Migranal	Dihydroergotamine Mesylate Nasal Spray 4 MG/ML	4 MG/ML	
Reyvow	lasmiditan succinate tab	100 MG ; 50 MG	
Trudhesa	dihydroergotamine mesylate hfa nasal aerosol	0.725 MG/ACT	

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Elyxyb	Celecoxib Oral Soln	120 MG/4.8ML	
Migranal	Dihydroergotamine Mesylate Nasal Spray 4 MG/ML	4 MG/ML	
Reyvow	Lasmiditan Succinate Tab 100 MG	100 MG	
Reyvow	Lasmiditan Succinate Tab 50 MG	50 MG	

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Trudhesa	Dihydroergotamine Mesylate HFA Nasal Aerosol	0.725 MG/ACT	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Indication	PDL Preferred Agents
Acute treatment of migraine with or without aura	Ubrelvy*
*For Ubrelvy - please see CGRP PAQL program	

Initial Evaluation

Target Agent(s) will be approved when ONE of the following is met:

1. ALL of the following:
    A. ONE of the following:
        1. The requested agent is being used for acute migraine treatment AND ALL of the following:
            A. ONE of the following:
                1. The patient's medication history includes at least one triptan agent AND ONE of the following:
                    A. The patient has had an inadequate response to at least one triptan agent **OR**
                    B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a triptan agent **OR**
                2. The patient has an intolerance or hypersensitivity to triptan therapy **OR**
                3. The patient has an FDA labeled contraindication to ALL triptan agents **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 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**
            B. ONE of the following:
                1. The requested agent is NOT Reyvow **OR**
                2. The requested agent is Reyvow and the patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, Elyxyb, ergotamine, triptan) **AND**
            C. Medication overuse headache has been ruled out **OR**

Module	Clinical Criteria for Approval
	2. The patient has another FDA approved indication for the requested agent and route of administration **OR** 3. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** B. If the patient has an FDA labeled indication, ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** C. ONE of the following: 1. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication **OR** 2. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication and ONE of the following: A. 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** B. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication as indicated by BOTH of the following: 1. ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** 2. ONE of the following: A. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) for the requested indication that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) 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** D. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Compendia Allowed:** CMS Approved Compendia

Module	Clinical Criteria for Approval
	Length of Approval: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ONE of the following is met: 1. ALL of the following: A. The patient has been approved for the requested agent previously through the Plan's Prior Authorization process **AND** B. ONE of the following: 1. The requested agent is being used for acute migraine treatment AND ALL of the following: A. The prescriber has provided information indicating improvement in acute migraine management with the requested agent **AND** B. ONE of the following: 1. The requested agent is NOT Reyvow **OR** 2. The requested agent is Reyvow AND the patient will NOT be using the requested agent in combination with another acute migraine therapy (i.e., 5HT-1F, acute use CGRP, Elyxyb, ergotamine, triptan) **AND** C. Medication overuse headache has been ruled out **OR** 2. BOTH of the following: A. ONE of the following: 1. The patient has another FDA approved indication for the requested agent and route of administration **OR** 2. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** B. The patient has had clinical benefit with the requested agent **AND** C. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA approved indication **AND** B. The patient uses an enteral tube for feeding or medication administration **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

Module	Clinical Criteria for Approval
	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) is greater than 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 program quantity limit **OR** 3. ALL of the following:

Module	Clinical Criteria for Approval
	A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. 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., 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., 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. The prescriber has provided information that the patient's migraines are manageable with acute therapy alone **AND** D. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Compendia Allowed:** CMS Approved Compendia **Length of Approval:** 12 months