

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Anti-Migraine Agents, Alternative Oral Agents PDL Edit
<b>First Implementation Date:</b>	October 1, 2020
<b>Proposed Date:</b>	December 17, 2020
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Migraines are a common episodic disorder that are described as a severe headache with or without aura that can be associated with nausea and/or light and sound sensitivity. Currently, it is assumed that migraines are caused by a primary neuronal dysfunction that leads to changes in both intracranial regions and extracranial regions. It is a disorder that affects up to 12% of the general population and more frequently in women than men. Although not fatal, migraines are a major cause of disability and are often intolerable. The following agents are all indicated for the acute treatment of migraine with or without aura in adults, but not indicated for the preventive treatment of migraine. Nurtec™ ODT (rimegepant) is a calcitonin gene-related peptide (CGRP) receptor antagonist which blocks pain signaling, vasodilation, and neurogenic inflammatory response. Its recommended dosing is a 75 mg single dose on/under the tongue with a maximum of 75 mg per 24 hours. The safety regarding treatment of more than 15 migraines in a 30-day period has not been clinically established yet. Ubrelyv™ (ubrogepant) is also a CGRP receptor antagonist that has a recommended dose of 50 mg or 100 mg taken orally as needed with no more than 200 mg taken per 24 hours. The safety regarding treatment of more than 8 migraines in a 30-day period has not been clinically established yet. Reyvow™ (lasmiditan) is a serotonin (5-HT) receptor agonist whose exact mechanism of action is not known. Its recommended dosing is 50 mg, 100 mg, or 200 mg taken orally as needed with no more than one dose taken per 24 hours. It is also recommended for participants to wait at least 8 hours after taking lasmiditan before driving or operating heavy machinery. Institute for Clinical Systems Improvement's Diagnosis and Treatment of Headache Guideline was last release in 2013 and has not been updated since, so these agents do not officially have a set place in therapy yet. However, they may serve to be the next step in therapy in participants who have tried NSAIDs or prescription antimigraine agents and did not have an adequate response to those treatments.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>Nurtec™ ODT</li> <li>Ubrelyv™</li> </ul>	<ul style="list-style-type: none"> <li>Reyvow™</li> </ul>

- Type of Criteria:  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit
- Data Sources:  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Anti-Migraine Agents, Alternative Oral Agents
- Age range: All appropriate MO HealthNet participants aged 18 or older

## Approval Criteria

- Adequate therapeutic trial of 2 triptan agents at up to maximally indicated doses, unless contraindicated (i.e. ischemic heart disease, stroke, uncontrolled hypertension) or clinically significant adverse effects are experienced **AND**
- Documented diagnosis of migraines **AND**
- Participants aged 18 years or older **AND**
- Failure to achieve desired therapeutic outcomes with trial on 1 preferred agent
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Nurtec ODT:
  - Not used in combination with other CGRP agents **AND**
  - Absence of severe hepatic impairment (Child-Pugh C) **OR**
- For Reyvow:
  - Absence of severe hepatic impairment (Child-Pugh C) **AND**
  - Adequate therapeutic trial (60/90 days) with 2 prophylactic options from 2 different categories including:
    - Anticonvulsants – divalproex, valproate, topiramate
    - Antidepressants – amitriptyline, venlafaxine
    - Beta blockers – atenolol, metoprolol, nadolol, propranolol, timolol **OR**
- For Ubrelvy:
  - Not used in combination with other CGRP agents
  - **Adequate therapeutic trial of lasmiditan (2 claims) AND**
  - **Adequate therapeutic trial (60/90 days) with 2 prophylactic options from 2 different categories including:**
    - **Anticonvulsants – divalproex, valproate, topiramate**
    - **Antidepressants – amitriptyline, venlafaxine**
    - **Beta blockers – atenolol, metoprolol, nadolol, propranolol, timolol**

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
NURTEC ODT 75MG	RIMEGEPANT	8 tablets per 30 days
UBRELVY 50MG	UBROGEPANT	10 tablets per 30 days
UBRELVY 100MG	UBROGEPANT	10 tablets per 30 days
REYVOW 50MG	LASMIDITAN	4 tablets per 30 days
REYVOW 100MG	LASMIDITAN	8 tablets per 30 days

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## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

1 year

## References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
4. Cutrer, F.M. (2020). Pathophysiology, clinical manifestations, and diagnosis of migraine in adults. In J.F. Dashe (Ed.). *UpToDate*.
5. Beithon J, Gallenberg M, Johnson K, Kildahl P, Krenik J, Liebow M, Linbo L, Myers C, Peterson S, Schmidt J, Swanson J. Institute for Clinical Systems Improvement. Diagnosis and Treatment of Headache. Updated January 2013.
6. Reyvow [package insert]. Indianapolis, IN: Eli Lilly and Company; 2020.
7. Ubrelvy [package insert]. Madison, NJ: Allergan; 2019.
8. Nurtec ODT [package insert]. New Haven, CT: Biohaven Pharmaceuticals Inc; 2020.
9. Evidence-Based Medicine and Fiscal Analysis: "Anti-Migraine, Alternative Oral Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; September 2020.
10. Evidence-Based Medicine Analysis: "Anti-Migraine, Alternative Oral Agents", UMKC-DIC; November 2020.

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