

SmartPA Criteria Proposal

Drug/Drug Class:	Anti-Migraine, Alternative Oral Agents PDL Edit
First Implementation Date:	October 1, 2020
Proposed Date:	December 16, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<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 and extracranial regions. It is a disorder that affects up to 12% of the general population and women more frequently 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. Nurtec® ODT (rimegepant) and Ubrelvy® (ubrogepant) are calcitonin gene-related peptide (CGRP) receptor antagonists that block pain signaling, vasodilation, and neurogenic inflammatory response. In May 2021, Nurtec became the first oral CGRP to gain the additional indication of preventive treatment of episodic migraine in adults. Reyvow® (lasmiditan) is a serotonin (5-HT) receptor agonist whose exact mechanism of action is unknown. It is recommended for participants to wait at least 8 hours after taking lasmiditan before driving or operating heavy machinery. In early 2021, the American Headache Society (AHS) published a Consensus Statement on migraines. Although triptans continue to be the mainstay of migraine treatment, the three agents in this class may be considered for moderate-to-severe attacks and mild-to-moderate attacks that poorly respond to non-specific therapy.

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"> Nurtec® ODT 	<ul style="list-style-type: none"> Reyvow® Ubrelvy®

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, 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~~
 - **When used for migraine prevention: adequate therapeutic trial of 2 injectable CGRP inhibitors**
- For Reyvow **and** Ubrelvy:
 - Adequate therapeutic with 2 prophylactic options from 2 different categories including:
 - Anticonvulsants – divalproex, valproate, topiramate
 - Antidepressants – amitriptyline, venlafaxine
 - Beta blockers – atenolol, metoprolol, nadolol, propranolol, timolol
 - **Injectable CGRPs inhibitors**

Denial Criteria

- Lack of adequate trial on required preferred agents
- For Nurtec and Reyvow: absence of severe hepatic impairment (Child-Pugh C)
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitations 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

*Up to 18 tablets per month will be allowed for migraine prevention when approval criteria is met

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

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

SmartPA PDL Proposal Form

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Default Approval Period

6 months

References

- Evidence-Based Medicine and Fiscal Analysis: “Anti-Migraine, Alternative Oral Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: “Anti-Migraine, Alternative Oral Agents”, UMKC-DIC; September 2021.
- Cutrer, F.M. (2020). Pathophysiology, clinical manifestations, and diagnosis of migraine in adults. In J.F. Dashe (Ed.). *UpToDate*.
- Ailani, J., Burch R.C., Robbins, M.S. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021; 00:1-19.
- USPDI, Micromedex; 2021.
- Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
- Nurtec ODT [package insert]. New Haven, CT: Biohaven Pharmaceuticals Inc; May 2021.
- Reyvow [package insert]. Indianapolis, IN: Eli Lilly and Company; January 2021.
- Ubrelvy [package insert]. Madison, NJ: Allergan; March 2021.