SmartPA Criteria Proposal

Drug/Drug Class:	Anti-Migraine, Alternative Oral Agents PDL Edit
First Implementation Date:	October 1, 2020
Revised Date:	April 6, 2023
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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 Ubrevly® (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
• Nurtec® ODT	• Reyvow® • Ubrelvy®

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☒ **Preferred Drug List**
☐ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

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Setting & Population

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

Approval Criteria

- Adequate therapeutic trial of 2 triptan agents at up to maximally indicated doses, unless contraindicated (i.e., ischemic heart disease, stroke) or clinically significant adverse effects are experienced **AND**
- Documented diagnosis of migraines **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 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
REVYOW 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:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

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

Default Approval Period

6 months

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References

- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: CENTRAL NERVOUS SYSTEM: Anti-Migraine, Alternative Oral Agents”, Gainwell Technologies; Last updated October 24, 2022.
- Evidence-Based Medicine Analysis: “Anti-Migraine, Alternative Oral Agents”, UMKC-DIC; September 2022.
- 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); 2022 Clinical Drug Information, LLC.
- Nurtec ODT [package insert]. New Haven, CT: Biohaven Pharmaceuticals Inc; April 2022.
- Reyvow [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2022.
- Ubrelvy [package insert]. Madison, NJ: Allergen; March 2021.

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