

Drug Policy

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| Policy: | Reyvow (Lasmiditan) | Annual Review Date: 11/16/2023 Last Revised Date: 11/16/2023 |
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OVERVIEW

Reyvow is the first approved drug in a new class of medications known as 5-HT_{1F} receptor agonists. Unlike the 5-HT_{1B/1D} triptans, Reyvow binds to 5-HT_{1F} receptors that are not found in the smooth muscle cells of the vasculature. Reyvow was proven to affect both freedom from pain and most bothersome symptom (MBS) at 2 hours in patients with migraine symptoms. Reyvow is indicated for the acute treatment of migraine with or without aura in adults.

POLICY STATEMENT

This policy involves the use of Reyvow. Prior authorization is recommended for pharmacy benefit coverage of Reyvow. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy, and Labs/Diagnostics** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Reyvow is recommended in those who meet the following criteria:

1. Acute Treatment of Migraine, With or Without Aura:

Criteria. Patient must meet the following criteria (A, B, C, D, E, F and G):

- A. Patient has a diagnosis of migraine, with or without aura, according to the International Classification of Headache Disorders (ICHD-3) (See **Appendix 1** below) **[Documentation required]**; AND
- B. The patient is 18 years or older; AND
- C. The requested medication is prescribed by a neurologist, pain specialist, ophthalmologist, or a physician certified in headache medicine; AND
- D. The provider has ruled out medication overuse as a possible cause of migraine; AND
- E. The severity of the patient's migraine is classified as moderate or severe; AND
- F. Patient agrees to **not** engage in potentially hazardous activities requiring complete alertness (i.e. driving or operating heavy machinery) for at least 8 hours after each dose of Reyvow; AND
- G. The patient meets one of the following criteria (i or ii):
 - i. The patient has trialed TWO triptan therapies with little to no relief of moderate/severe migraine symptoms; OR

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- ii. The patient has a contraindication to triptan therapy.

Initial Approval/ Extended Approval.

A) *Initial Approval:* 3 Months (90 days)

B) *Extended Approval:* 1 Year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Reyvow has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Preventative treatment of chronic migraine
2. Cluster headaches
3. Hemiplegic migraines
4. Reyvow is not recommended for use concurrently with triptan therapies.
5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Lipton RB, Bigal ME, Diamond M, et al. Migraine prevalence, disease burden, and the need for preventive therapy. *Neurology*. 2007;68(5):343-349. Doi;
2. Reyvow [prescribing information]. Indianapolis, IN: Eli Lilly and Company; July 2020
3. Olesen J, Bolay H, et al. The International Classification of Headache Disorders, 3rd edition. *Cephalgia*. 2018;38(1): 1-211.
4. Mayans L, Walling A, et al. Acute Migraine Headache: Treatment Strategies. *Am Fam Physician*. 2018 Feb 15;97(4):243-251.
5. Marmura MJ1, Silberstein SD, Schwedt TJ. The acute treatment of migraine in adults: the american headache society evidence assessment of migraine pharmacotherapies. *Headache*. 2015 Jan;55(1):3-20. doi: 10.1111/head.12499.

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Appendix 1: International Headache Society Criteria for Migraine Diagnosis (ICHD-3)

| Migraine without aura | Migraine with aura |
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| <p>A. At least five attacks fulfilling criteria B–D</p> <p>B. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)</p> <p>C. Headache has at least two of the following four characteristics:</p> <ol style="list-style-type: none"> 1. unilateral location 2. pulsating quality 3. moderate or severe pain intensity 4. aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) <p>D. During headache at least one of the following:</p> <ol style="list-style-type: none"> 1. nausea and/or vomiting 2. photophobia and phonophobia <p>E. Not better accounted for by another ICHD-3 diagnosis.</p> | <p>A. At least two attacks fulfilling criteria B and C</p> <p>B. One or more of the following fully reversible aura symptoms:</p> <ol style="list-style-type: none"> 1. visual 2. sensory 3. speech and/or language 4. motor 5. brainstem 6. retinal <p>C. At least three of the following six characteristics:</p> <ol style="list-style-type: none"> 1. at least one aura symptom spreads gradually over ≥ 5 minutes 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 <p>D. Not better accounted for by another ICHD-3 diagnosis</p> |