

Clinical Policy: Lasmiditan (Reyvow)

Reference Number: IL.PMN.218

Effective Date: 1.1.20

Last Review Date: 9.9.22

[Revision Log](#)

Line of Business: Medicaid

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Lasmiditan (Reyvow™) is a serotonin (5-HT) 1F agonist.

FDA Approved Indication(s)

Reyvow is indicated for the acute treatment of migraine with or without aura in adults.

Limitation(s) of use: Reyvow is not indicated for the preventive treatment of migraine.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Reyvow is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Migraines (must meet all):

1. Diagnosis of migraine headaches;
2. Age ≥ 18 years;
3. Failure of at least TWO formulary 5HT_{1B/1D}-agonist migraine medications (e.g., sumatriptan, rizatriptan) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. For requests for quantities greater than two doses per month, member meets one of the following (a or b):
 - a. Failure of TWO prophylactic migraine medications, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B*);
 - b. Member is being treated by or in consultation with a neurologist or a headache specialist;
5. Dose does not exceed 200 mg (1 tablets) per day and 4 days per month.

Approval duration:

Medicaid – 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Migraines (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 200 mg (1 tablets) per day and 4 days per month.

Approval duration:

Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

5-HT: serotonin

AAN: American Academy of Neurology

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|--|-----------------------------|
| sumatriptan (Imitrex [®] nasal spray) | One spray (5 – 20mg) at onset into one nostril; can be repeated in 2 hours | 40 mg/day |
| sumatriptan (Imitrex [®]) | One tablet (25 -100mg) PO at onset; can be repeated in two hours | 200 mg/day |
| rizatriptan (Maxalt [®] /Maxalt MLT [®]) | One tablet (5 or 10 mg) PO at onset of migraine headache; can be repeated in two hours | 30 mg/day |
| Preventive Therapies for Migraine (Adopted by the American Academy of Neurology [AAN]) | | |
| Medication | Dose | Level of Evidence** |
| Anticonvulsants | | |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|--------------------------|-----------------------------|
| divalproex sodium (Depakote [®]) | 500-1,000 mg/day PO | FDA-approved |
| divalproex sodium ER (Depakote [®] ER) | 500-1,000 mg/day PO | FDA-approved |
| gabapentin (Neurontin [®]) | 900-2,400 mg/day PO | Group II |
| topiramate (Topamax [®]) | 100 mg/day PO | FDA-approved |
| Beta-Blockers | | |
| atenolol (Tenormin [®]) | 100 mg/day PO | Group II |
| metoprolol (Lopressor [®]) | 200 mg/day PO | Group II |
| nadolol (Corgard [®]) | 80-240 mg/day PO | Group II |
| propranolol (Inderal [®]) | 80-240 mg/day PO | Group I |
| timolol (Blocadren [®]) | 20-30 mg/day PO | Group I |
| Calcium Channel Blockers | | |
| verapamil (Calan [®]) | 240 mg/day PO | Group II |
| SSRIs | | |
| fluoxetine (Prozac [®]) | 20 mg QOD - 40 mg/day PO | Group II |
| Tricyclic Antidepressants | | |
| amitriptyline (Elavil [®]) | 30-150 mg/day PO | Group I |
| imipramine (Tofranil [®]) | Not established | Group III |
| nortriptyline (Pamelor [®]) | Not established | Group III |

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- The AAN recommends that prophylactic migraine medications should be considered if the patient experiences 2 or more attacks per month that produce aggregate disability of 3 or more days/month.
- The AAN and the National Headache Foundation recommend that prophylactic migraine medications should be considered if one or more of the following are present: greater than 2 migraine headaches per week; migraines cause significant impairment in daily routine even with abortive treatment; contraindication to, adverse effects, overuse or failure of abortive migraine medications, presence of uncommon migraine condition (e.g., basilar migraine); or patient requesting prophylactic therapy.

V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|------------|--|--------------|
| Migraines | 50 mg, 100 mg, or 200 mg taken orally, as needed | 200 mg/dose |

VI. Product Availability

Tablets: 50 mg, 100 mg, 200 mg

VII. References

1. Reyvow Prescribing Information. Indianapolis, IN: Lilly USA, LLC; January 2021. Available at: <https://uspl.lilly.com/reyvow/reyvow.html#pi>. Accessed July 1, 2021.
2. Kuca B, Silberstein SD, Wietecha L, et al. Lasmiditan is an effective acute treatment for migraine. *Neurology*. 2018;91:e2222-32.
3. Goadsby PJ, Wietecha LA, Dennehy EB, et al. Phase 3 randomized, placebo-controlled, double-blind study of lasmiditan for acute treatment of migraine. *Brain*. 2019;142:1894-1904.
4. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
5. MICROMEDEX[®] Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 12, 2020.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|----------|-------------------|
| Policy created, adapted from CP.PMN.218 Lasmiditan (Reyvow) for migration to HFS PDL. | 12.30.19 | 1.7.20 |
| 2Q 2021 Annual review: no significant changes. References reviewed and updated. | 4.20.21 | |
| RT4: Changes Added new dose 200 mg tablet | 9.2.21 | |
| 3Q2022 Annual review: no significant changes; references reviewed. | 9.9.22 | |

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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