Clinical Policy: Lasmiditan (Reyvow)

Reference Number: ERX.NPA.133
Effective Date: 03.01.20
Last Review Date: 02.21
Line of Business: Commercial, Medicaid

Revision Log

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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, zolmitriptan) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
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 clinically significant adverse effects are experienced or all are contraindicated (*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 tablet) per day and 4 days per month.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Migraines (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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 tablet) per day and 4 days per month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
naratriptan (Amerge®)	One tablet (1 or 2.5 mg) PO at onset; can be repeated in 4 hours	5 mg/day
almotriptan (Axert®)	6.25 to 12.5 mg PO QD May repeat dose in 2 hours	25 mg/day
frovatriptan (Frova®)	2.5 mg PO QD May repeat dose in 2 hours	7.5 mg/day
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
eletriptan (Relpax®)	20 or 40 mg PO QD May repeat dose in 2 hours	40 mg/dose 80 mg/day
zolmitriptan (Zomig®/Zomig® ZMT)	1.25 or 2.5 mg PO QD May repeat dose in 2 hours	5 mg/dose 10 mg/day

Preventive Therapies for Migraine (Adopted by the American Academy of Neurology [AAN])		
Medication	**Dose**	**Level of Evidence****
Anticonvulsants		
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

Preventive Therapies for Migraine (Adopted by the American Academy of Neurology [AAN])		
Medication	**Dose**	**Level of Evidence****
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 PO, as needed	200 mg/dose

VI. Product Availability
Tablets: 50 mg, 100 mg, 200mg

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	11.19.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	11.12.20	02.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT4: added new dose strength of 200mg tablet	07.01.21	

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.