

Clinical Policy: Ubrogepant (Ubrelevy)

Reference Number: ERX.SPA.378

Effective Date: 06.01.20

Last Review Date: 05.21

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Ubrogepant (Ubrelevy™) is a calcitonin gene-related peptide (CGRP) receptor antagonist.

FDA Approved Indication(s)

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

Limitation(s) of use: Ubrelevy 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 Ubrelevy 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 contraindicated or clinically significant adverse effects are experienced;
4. For requests for monthly quantities > 1 box of 10 tablets per month, member meets all of the following (a, b, and c):
 - a. Failure of TWO oral migraine prophylactic therapies from different therapeutic classes, each for 8 weeks, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*);
**Prior authorization may be required.*
 - b. Failure of a 3-month trial of ONE CGRP inhibitor* used for migraine prophylaxis, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*);
**Prior authorization may be required.*
 - c. Member is being treated by or in consultation with a neurologist, headache, or pain specialist;
5. Ubrelevy is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy™, Emgality™, Nurtec® ODT);
6. Dose does not exceed 200 mg (2 tablets) per day and 8 days per month.

Approval duration: 6 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. For dose increase requests to quantities > 1 box of 10 tablets per month, member meets all of the following (a, b, and c):
 - a. Failure of TWO oral migraine prophylactic therapies from different therapeutic classes, each for 8 weeks, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*);
**Prior authorization may be required.*
 - b. Failure of a 3-month trial of ONE CGRP inhibitor* used for migraine prophylaxis, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*);
**Prior authorization may be required.*
 - c. Member is being treated by or in consultation with a neurologist, headache, or pain specialist;
4. Ubrely is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality, Nurtec ODT);
5. If request is for a dose increase, new dose does not exceed 200 mg (2 tablets) per day and 8 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

CGRP: calcitonin gene-related peptide

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 – 20 mg) at onset into one nostril; can be repeated in 2 hours	40 mg/day
sumatriptan (Imitrex®)	One tablet (25 -100 mg) PO at onset; can be repeated in two hours	200 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
Antiepileptic Drugs**		
divalproex sodium (Depakote®)	500-1,000 mg/day PO	1,000 mg/day
divalproex sodium ER (Depakote® ER)	500-1,000 mg/day PO	1,000 mg/day
topiramate (Topamax®)	100 mg/day PO	100 mg/day
Beta-Blockers		
metoprolol (Lopressor®)	200 mg/day PO	200 mg/day
propranolol (Inderal®)	80 to 240 mg/day PO	240 mg/day
timolol (Blocadren®)	20 to 30 mg/day PO	30 mg/day
atenolol (Tenormin®)	100 mg/day PO	100 mg/day
nadolol (Corgard®)	80 to 240 mg/day PO	240 mg/day
SSRIs		
venlafaxine XR (Effexor XR®)	150 mg/day PO	150 mg/day
Tricyclic Antidepressants		
amitriptyline (Elavil®)	30 to 150 mg/day PO	150 mg/day
CGRP Inhibitors**		
Aimovig (erenumab)	70 mg SC once a month; may be increased to 140 mg SC once a month	140 mg/month
Ajovy (fremanezumab)	225 mg SC once a month or 675 mg SC every 3 months	225 mg/month or 675 mg/3 months
Emgality (galcanezumab)	240 mg SC as a single loading dose, followed by 120 mg SC once a month	120 mg/month

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.

**FDA approved.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concomitant use with strong CYP3A4 inhibitors
- Boxed warning(s): 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 or 100 mg PO, as needed. If needed, a second dose may be administered at least 2 hours after the initial dose. The maximum dose in a 24-hour period is 200 mg.	200 mg/day

VI. Product Availability

Tablets (package size 10, 12, 30): 50 mg, 100 mg

VII. References

1. Ubrelvy Prescribing Information. Madison, NJ: Allergan USA, Inc.; December 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211765s000lbl.pdf. Accessed February 17, 2021.
2. Dodick DW, Lipton RB, Ailani J, et al. Ubrogепant for the Treatment of Migraine. N Engl J Med 2019 Dec 5; 381:2230-41.
3. Lipton RB, Dodick DW, Ailani J, et al. Effect of Ubrogепant vs Placebo on Pain and the Most Bothersome associated symptom in the acute treatment of migraine: the ACHIEVE II randomized clinical trial. JAMA 2019; 322(10):1887-98.
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 February 17, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	02.04.20	05.20
Revised requirement 'for monthly quantities > 1 box of 6 tablets per month' to 10 tablets per month as this is the smallest available package size. Updated Section VI to remove the 6 and 8 tablet package sizes.	06.08.20	08.20
2Q 2021 annual review: no significant changes; references reviewed and updated.	02.17.21	05.21

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.

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