Clinical Policy: Ubrogepant (Ubrelvy)

Reference Number: CP.PHAR.476
Effective Date: 06.01.20
Last Review Date: 11.22
Line of Business: Medicaid

Revision Log

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

Description

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

FDA Approved Indication(s)

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

Limitation(s) of use: Ubrelvy 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 Ubrelvy 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 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. Ubrelvy is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy™, Emgality™, Nurtec® ODT, Qulipta™, Vyepti™);
6. Dose does not exceed 200 mg (2 tablets) per day and 8 days per month.

Approval duration: 6 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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 at least 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. Ubrelvy is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy, Emgality, Nurtec ODT, Qulipta, Vyepti);*
   **This requirement does not apply to CA if member was previously approved via Centene benefit and is currently stable on therapy with both oral and injectable CGRP inhibitors*
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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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
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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Abortive Migraine Therapy		
Triptans		
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 to 20 mg) at onset into one nostril; can be repeated in 2 hours	40 mg/day
sumatriptan (Imitrex®)	One tablet (25 to 100 mg) 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
Prophylactic Migraine Therapy		
Antiepileptic Drugs*		
divalproex sodium (Depakote®)	500 to 1,000 mg/day PO	1,000 mg/day
divalproex sodium ER (Depakote® ER)	500 to 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
Serotonin Reuptake Inhibitors		
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
Vyepti (eptinezumab-jjmr)	The recommended dosage is 100 mg IV every 3 months. Some patients may benefit from a dosage of 300 mg IV every 3 months.	300 mg every 3 months
Nurtec ODT (rimegepant)	Acute migraine treatment: 75 mg PO as needed Migraine prophylaxis: 75 mg PO every other day	See dosing regimen
Qulipta (atogepant)	10 mg, 30 mg, or 60 mg PO QD	60 mg/day

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, 16, 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 July 27, 2022.
2. Dodick DW, Lipton RB, Ailani J, et al. Ubrogepant 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 ubrogepant 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 July 27, 2022.

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2021 annual review: no significant changes; revised reference to HIM off-label use policy from HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	02.17.21	05.21
Added clarification in continuation of therapy to indicate requirement for concurrent use with other CGRP inhibitors does not apply to CA if member was previously approved via Centene benefit and is currently stable on therapy with both oral and injectable CGRP inhibitors.	06.28.21	
1Q 2022 annual review: no significant changes; references reviewed and updated.	09.15.21	02.22
4Q 2022 annual review: per August SDC and prior clinical guidance removed Commercial and HIM lines of business (Ubrelvy will be added to step therapy policies CP.CPA.83 and HIM.PA.109); references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.27.22	11.22

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.