RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	**Ubrelvy**
Policy Number:	RxA.630
Drug(s) Applied:	Ubrelvy™
Original Policy Date:	05/10/2020
Last Review Date:	05/10/2020
Line of Business Policy Applies to:	Commercial, Medicaid

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
ubrogepant (Ubrelvy)	Acute treatment of migraine with or without aura in adults	50 mg or 100 mg PO once as needed; a second dose may be taken at least 2 hours after the initial dose. Severe renal impairment (CrCl 15-29 mL/min) or severe hepatic impairment (Child-Pugh Class C): 50 mg PO once as needed; a second 50 mg dose may be taken at least 2 hours after the initial dose.	200 mg in 24-hour period

Dosage Forms

- Tablets: 50 mg, 100 mg

Clinical Policy

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

I. Initial Approval Criteria

A. Migraines (must meet all):

1. Diagnosis of migraine headaches;
2. Age ≥ 18 years;
3. Failure of at least two preferred generic $5HT_{1B/1D}$-agonist migraine medications (e.g., sumatriptan, rizatriptan, zolmitriptan, etc) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

4. Requested quantity does not exceed 16 tablets per 30 days;
5. If requested quantity is greater than 16 tablets over 30 days, member must meet one of the following (a or b):
   a. Failure of two prophylactic migraine medications unless contraindicated, from at least two different categories, each consisting of a 3-month trial *(see Appendix B)*;
   b. Patient is being treated by or in consultation with a neurologist or a headache specialist;

Approval Duration:
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Migraines (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy
3. If request is for a dose increase, new quantity does not exceed 16 tablets per 30 days;
4. If requested quantity is greater than 16 tablets over 30 days, member must meet one of the following (a or b):
   a. Failure of two prophylactic migraine medications unless contraindicated, from at least two different categories, each consisting of a 3-month trial *(see Appendix B)*;
   b. Patient is being treated by or in consultation with a neurologist or a headache specialist;

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CGRP: calcitonin gene-related peptide
CrCl: creatinine clearance
PO: oral

APPENDIX B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. Please refer to Micromedex® for dosing recommendations.

Drug Class	Examples
Anticonvulsants	divalproex sodium, sodium valproate, topiramate
Antidepressants	amitriptyline
Beta blockers	atenolol, nadolol, metoprolol, propranolol, timolol
Calcium channel blockers	verapamil
Preventive CGRPs	Aimovig, Ajovy

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None

- Boxed Warning(s):
  - None

APPENDIX D: General Information

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)
- Patient requesting prophylactic therapy.

References

1. Ubrelvy Prescribing Information. Madison, NJ; Allergan USA, Inc: December 2019. Available at https://www.allergan.com/products/Ubrelvy. Accessed May 10, 2020.
2. Mayans L, Walling A. Acute Migraine Headache: Treatment Strategies. Am Fam Physician. 2018;97(4):243-251.
3. Updated: Pharmacologic Treatment for Episodic Megraine Prevention in Adults. American Academy of Neurology. https://www.aan.com/Guidelines/Home/GuidelineDetail/536. Published April 2012. Updated July 2015. Accessed May 10, 2020.
4. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	05/10/2020	05/21/2020