Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2020**
Policy Number: PA.CP.PHAR.476	**Effective Date: 05/2020** **Revision Date: 05/2020**
Policy Name: Ubrogepant (Ubrelvy)	

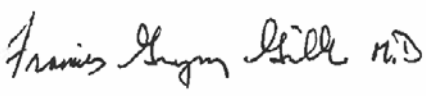
Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy Created

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Ubrogepant (Ubrelvy)

Reference Number: PA.CP.PHAR.476
Effective Date: 05/2020
Last Review Date: 05/2020 Revision Log

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 PA Health & Wellness 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 (see https://papdl.com/preferred-drug-list for list of preferred agents) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. For requests for quantities greater than 8 tablets 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. Ubrelvy is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy™, Emgality™);
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 the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. For requests for quantities greater than 8 tablets 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;
4. Ubrelvy is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy™, Emgality™);
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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

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.

Abortive Migraine Therapy		
Drug Name	**Dosing Regimen**	**Dose Limit/Maximum Dose**
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

Abortive Migraine Therapy		
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
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		
Drug Name	**Dosing Regimen**	**Level of Evidence***
Antiepileptic Drugs*		
divalproex sodium (Depakote®)	500 to 1,000 mg/day PO	Level A (AAN; AHS)
divalproex sodium ER (Depakote® ER)	500 to 1,000 mg/day PO	Level A (AAN; AHS)
topiramate (Topamax®)	100 mg/day PO	Level A (AAN; AHS)
Beta-Blockers		
metoprolol (Lopressor®)	200 mg/day PO	Level A (AAN; AHS)
propranolol (Inderal®)	80 to 240 mg/day PO	Level A (AAN; AHS)
timolol (Blocadren®)	20 to 30 mg/day PO	Level A (AAN; AHS)
atenolol (Tenormin®)	100 mg/day PO	Level B (AAN; AHS)
nadolol (Corgard®)	80 to 240 mg/day PO	Level B (AAN; AHS)
Serotonin Reuptake Inhibitors		
venlafaxine XR (Effexor XR®)	150 mg/day PO	Level B (AAN; AHS)
Tricyclic Antidepressants		
amitriptyline (Elavil®)	30 to 150 mg/day PO	Level B (AAN; AHS)
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

Prophylactic Migraine Therapy		
Drug Name	**Dosing Regimen**	**Level of Evidence***
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.
**American Headache Society (AHS) 2018, American Academy of Neurology (AAN) 2012: Level A: established efficacy, Level B: probably effective, Level C: possibly effective.*
***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 6, 8, 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 January 23, 2020.
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 January 27, 2020.

Reviews, Revisions, and Approvals	Revision Date
Policy created	04/2020