Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	NA	X	X	X	NA

Ubrelvy (ubrogepant)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Ubrelvy (ubrogepant) 50 mg, 100 mg tablets	16 tablets per 30 days*

*For approval of up to a maximum of 32 – 50 mg tablets or 32 – 100 mg tablets per 30 days per rolling 30 days, the individual must meet the following criteria:

I. Individual has a diagnosis of migraine headaches; **AND**
II. Individual has had a previous trial and an inadequate response to **one** of the following daily preventive therapies (AAN/AHA 2012/2015, ICSI 2013):
    A. A tricyclic antidepressant [such as but not limited to amitriptyline, doxepin]; **OR**
    B. A beta blocker [such as but not limited to metoprolol tartrate, propranolol, timolol, atenolol, nadolol, nebivolol]; **OR**
    C. A calcium channel blocker [such as but not limited to nicardipine, verapamil]; **OR**
    D. An ACE inhibitor [such as but not limited to lisinopril]; **OR**
    E. An angiotensin receptor blocker (ARBs) [such as but not limited to candesartan]; **OR**
    F. An alpha-2 agonist [such as but not limited to guanfacine]; **OR**
    G. An antiepileptic [such as but not limited to divalproex sodium, sodium valproate, topiramate, carbamazepine, gabapentin]; **OR**
    H. Other select antidepressants [such as but not limited to venlafaxine]; **OR**
    I. Cyproheptadine (Periactin).

APPROVAL CRITERIA

Requests for Ubrelvy (ubrogepant) may be approved if the following criteria is met:

I. Documentation is provided that individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to **two** preferred oral triptans;

    Preferred oral agents: naratriptan (generic Amerge), sumatriptan (generic Imitrex).

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Applicable	X	NA	X	X	X	NA

OR

II. Documentation is provided that individual has one of the following cardiovascular or non-coronary vascular contraindications to use of triptans:
   A. Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina); **OR**
   B. History of stroke or transient ischemic attack (TIA); **OR**
   C. Peripheral vascular disease; **OR**
   D. Ischemic bowel disease; **OR**
   E. Uncontrolled hypertension;

AND

III. Documentation is provided that individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to Nurtec ODT;

OR

IV. Documentation is provided for one of the following contraindications to use of Nurtec ODT that is not also present with Ubrelvy:
   A. Individual currently using a strong or moderate CYP3A4 inducer (including but not limited to carbamazepine, phenytoin, St. John's wort, modafinil, rifampin); **OR**
   B. Individual currently using a P-glycoprotein (P-gp) or BCRP inhibitor (including but not limited to ketoconazole, quinidine, tacrolimus, verapamil, sulfasalazine); **OR**
   C. Individual with severe hepatic impairment (Child-Pugh C); **OR**
   A. Individual with end-stage renal disease (CrCl < 15 mL/min).

Ubrelvy (ubrogepant) may not be approved for the following:

I. Individual is currently using a strong CYP3A4 inhibitor (such as ketoconazole, itraconazole, clarithromycin).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 14, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Beithon J, Gallenberg M, Johnson K, et al. Diagnosis and Treatment of Headache. Institute for Clinical Systems Improvement. Available from: https://www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_neurological_guidelines/headache/. Updated January 2013.
6. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019; 59:1-18. Available from: https://onlinelibrary.wiley.com/doi/epdf/10.1111/head.13456. Accessed November 26, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	NA	X	X	X	NA

7. Tfelt-Hansen PC. Triptans and ergot alkaloids in the acute treatment of migraine: similarities and differences. *Expert Rev Neurother.* 2013; 13(9): 961-963. Available from https://www.tandfonline.com/doi/pdf/10.1586/14737175.2013.832851. Accessed April 5, 2019.
8. Ubrelvy (ubrogepant) [package insert]. Madison, NJ: Allergan USA, Inc.; 2019.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.