MEDICAL MUTUAL®

Drug Policy

Policy:	Acute Oral CGRP Antagonists • Ubrelvy (ubrogepant) • Nurtec ODT (rimegepant)	Annual Review Date: 01/20/2021 Last Revised Date: 02/18/2021

OVERVIEW

Nurtec ODT and Ubrelvy are oral calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine with or without aura in adults. Unlike the large molecule injectable CGRPs approved for the prevention of migraines, Nurtec ODT and Ubrelvy are small molecule CGRP antagonist that passes through the blood brain barrier to stop a migraine in progress. Ubrelvy also does not have the cardiovascular concerns associated with other usual acute migraine treatments such as triptans.

POLICY STATEMENT

This policy involves the use of Nurtec ODT and Ubrelvy. Prior authorization is recommended for pharmacy benefit coverage of Nurtec ODT and Ubrelvy. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Nurtec ODT and Ubrelvy as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Nurtec ODT and Ubrelvy be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Nurtec ODT and Ubrelvy is recommended in those who meet the following criteria:

1. <u>Acute Treatment of Migraine With or Without Aura.</u>
Criteria. *Patient must meet the following criteria (A, B, C, D, E, <u>and</u> F):*

- **A.** Patient has a diagnosis of migraine, with or without aura, according to the International Classification of Headache Disorders (ICHD-3) (See **Appendix 1** below) [Documentation required]; AND
- **B.** The patient is 18 years or older; AND
- **C.** The requested medication is prescribed by or in consultation with a neurologist, pain specialist, ophthalmologist, or a physician certified in headache medicine; AND
- **D.** The provider has ruled out medication overuse as a possible cause of migraine; AND

E. The severity of the patient's migraine is classified as moderate or severe; AND
F. The patient meets one of the following criteria (i or ii):
  i. The patient has tried at least TWO generic triptan therapies with little to no relief of moderate/severe migraine symptoms; OR
  ii. The patient has a contraindication to triptan therapy.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 90 days
B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Nurtec ODT and Ubrelvy has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Preventative treatment of chronic migraine

2. Concomitant use with strong CYP3A4 inhibitors(e.g. ketoconazole, itraconazole, clarithromycin)

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Ubrelvy [prescribing information]. Madison, NJ: Allergan Pharmaceuticals International: December, 2019
2. Olesen J, Bolay H, et al. The International Classification of Headache Disorders, 3rd edition. *Cephalagia*. 2018;38(1): 1-211.
3. Nurtec ODT [prescribing information]. New Haven, CT: Biohave Pharmaceuticals: February 2020.

Appendix 1: International Headache Society Criteria for Migraine Diagnosis (ICHD-3)

Migraine without aura	Migraine with aura
A. At least five attacks fulfilling criteria B–D B. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated) C. Headache has at least two of the following four characteristics: 1. unilateral location 2. pulsating quality 3. moderate or severe pain intensity 4. aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) D. During headache at least one of the following: 1. nausea and/or vomiting 2. photophobia and phonophobia E. Not better accounted for by another ICHD-3 diagnosis.	A. At least two attacks fulfilling criteria B and C B. One or more of the following fully reversible aura symptoms: 1. visual 2. sensory 3. speech and/or language 4. motor 5. brainstem 6. retinal C. At least three of the following six characteristics: 1. at least one aura symptom spreads gradually over ≥5 minutes 2. two or more aura symptoms occur in succession 3. each individual aura symptom lasts 5-60 minutes 4. at least one aura symptom is unilateral 5. at least one aura symptom is positive 6. the aura is accompanied, or followed within 60 minutes, by headache D. Not better accounted for by another ICHD-3 diagnosis