PRIOR AUTHORIZATION POLICY

POLICY: Migraine – Ubrelvy™ (ubrogepant tablet – Allergan)

DATE REVIEWED: 01/29/2020; selected revision 06/03/2020

OVERVIEW
Ubrelvy, a calcitonin gene-related peptide receptor antagonist, is indicated for the acute treatment of migraine headache with or without aura in adults.[1] Limitations of Use: Ubrelvy is not indicated for the preventive treatment of migraine. The recommended dose of Ubrelvy is 50 mg or 100 mg taken orally with or without food. If needed, a second dose may be taken ≥ 2 hours after the initial dose. The maximum dose in a 24-hour period is 200 mg. The safety of treating more than 8 migraines in a 30-day period has not been established.

Disease Overview

Migraine is a common, ongoing condition marked by paroxysmal, unilateral attacks of moderate to severe throbbing headache which is aggravated by routine physical activity (e.g., walking or climbing stairs) and associated with nausea, vomiting, and/or photophobia and phonophobia.[2] Migraine headache episodes typically last 4 to 72 hours, if untreated. Migraine affects approximately 15% of US adults.[3] Migraines have been defined as chronic or episodic. Chronic migraine is described by the International Headache Society as headache occurring on ≥ 15 days/month for more than 3 months, which has the features of migraine headache on ≥ 8 days/month.[2] Episodic migraine is characterized by headaches that occur < 15 days/month.[4] Patients with episodic migraine may transform to chronic migraine over time at a rate of about 2.5% of patients per year. Potential strategies for preventing migraine transformation include preventing and treating headaches, lifestyle modifications, or effective management of comorbidities (e.g., obesity, obstructive sleep apnea, depression, anxiety). Episodic migraine is more common than chronic migraine; however, chronic migraine is associated with a markedly greater personal and societal burden.

Triptans (e.g., almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan) are considered the gold standard for acute treatment of moderate to severe migraine headaches or mild to moderate migraine headaches that respond poorly to over-the-counter (OTC) analgesics. An updated assessment of the **preventive and acute treatment of migraine by the American Headache Society** (2018) lists the triptans and dihydroergotamine as effective treatments for moderate or severe acute migraine attacks and mild to moderate attacks that respond poorly to nonsteroidal anti-inflammatory drugs (NSAIDs) or caffeinated combinations (e.g., aspirin + acetaminophen + caffeine).[5] Treat at the first sign of pain to improve the probability of achieving freedom from pain and reduce attack-related disability.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Ubrelvy. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Ubrelvy is recommended in those who meet the following criteria:

FDA-Approved Indications

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1. **Migraine, Acute Treatment.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) The patient is ≥ 18 years of age; AND
   B) The patient meets ONE of the following (i or ii):
      i. The patient has tried at least one triptan therapy; OR
      ii. The patient has a contraindication to triptan(s) according to the prescriber.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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.

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

REFERENCES

1. Ubrelvy™ tablets [prescribing information]. Madison, NJ: Allergan; December 2019.
2. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 3rd edition (beta version). *Cephalalgia*. 2013;33:629-808.
3. MacGregor EA. In the clinic. Migraine. *Ann Intern Med*. 2017;166(7):ITC49-ITC64.
4. Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. *Headache*. 2015;52:103-122.
5. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.