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Ubrogепant

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Related Coverage Resources

Quantity Limitations - (1201)

INSTRUCTIONS FOR USE

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Overview

This policy supports medical necessity review for Ubrelvy® (ubrogепant) tablet.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Ubrogепant (Ubrelvy) is considered medically necessary when the following are met:

- 1. Treatment of Acute Migraine. Individual meets BOTH of the following criteria (A and B):
A. Individual is 18 years of age or older
B. Documentation of ONE of the following (i or ii):
i. Individual has had an inadequate response to at least ONE triptan (for example, almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan)
ii. Individual has a contraindication or intolerance to triptans.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Ubrogepant (Ubrelyv) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months.
Reauthorization approval duration: up to 12 months.

Conditions Not Covered

Ubrogepant (Ubrelyv) is considered experimental, investigational or unproven for **ANY** other use including the following (this list may not be all inclusive):

- 1. Concurrent use (for example, during the same time period) of two CGRP inhibitors indicated for the acute treatment of migraine (for example Nurtec ODT and Ubrelyv)**
Insufficient information exists from controlled trials and evidence based professional organizations on concurrent use of two CGRP inhibitors.

Background

OVERVIEW

Ubrelyv, 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: Ubrelyv is not indicated for the preventive treatment of migraine.

Disease Overview

Migraine is a common, ongoing condition marked by paroxysmal, unilateral attacks of moderate to severe throbbing headache which are aggravated by routine physical activity (e.g., walking or climbing stairs) and associated with nausea, vomiting, and/or photophobia and phonophobia.² 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. Episodic migraine is characterized by headaches that occur < 15 days/month.³

Guidelines

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 analgesics. An assessment of the preventive and acute treatment of migraine by the American Headache Society (2018; updated 2021) reaffirms previous migraine guidelines.^{4,5} The update lists the triptans, dihydroergotamine, the oral gepants (Nurtec[®] ODT [rimegepant orally disintegrating tablets,] and Ubrelyv[®] [ubrogepant tablets]), and Reyvow[®] (lasmiditan tablets) as effective treatments for moderate or severe acute migraine attacks and mild to moderate attacks that respond poorly to nonsteroidal anti-inflammatory drugs, non-opioid analgesics, acetaminophen, or caffeinated combinations (e.g., aspirin + acetaminophen + caffeine). The recommendation remains that clinicians must consider medication efficacy and potential medication-related adverse events when prescribing acute medications for migraine.

References

1. Ubrelvy® tablets [prescribing information]. Madison, NJ: Allergan; March 2021.
2. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 3rd edition. *Cephalalgia*. 2018;38(1):1-211.
3. Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. *Headache*. 2015;52:103-122.
4. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
5. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021;61(7):1021-1039.

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