

Federal Employee Program.

MIGRAINE CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS ORAL Nurtec ODT (rimegepant), Qulipta (atogepant), Ubrelvy* (ubrogepant)

*Prior authorization for this product applies only to formulary exceptions due to being a noncovered medication

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Nurtec ODT (rimegepant), Qulipta (atogepant), and Ubrelvy (ubrogepant) are calcitonin generelated peptide receptor (CGRP) antagonists. CGRP is a neuropeptide widely distributed in the nervous system, particularly at anatomical areas thought to be involved with migraine, including the trigeminovascular nociceptive system. In studies, CGRP has been shown to be released during severe migraine attacks. CGRP mechanism blockade either by small molecule receptor antagonists or by monoclonal antibodies can have an abortive or preventive effect in migraine (1-4).

Regulatory Status

FDA-approved indications: (1-3)

- Nurtec ODT and Ubrelvy are indicated for the acute treatment of migraine with or without aura in adults.
- Nurtec ODT is also indicated for the preventative treatment of episodic migraine in adults.
- Qulipta is indicated for the preventative treatment of migraine in adults.

<u>Limitations of Use</u>: Ubrelvy is not indicated for the preventative treatment of migraine (1). The recommended dose of Nurtec ODT for acute treatment is 75 mg taken orally, as needed. The maximum dose in a 24-hour period is 75 mg. The safety of using more than 18 doses in a 30-day period has not been established. The recommended dose of Nurtec ODT for preventative treatment is 75 mg taken orally every other day (3).

The recommended dosage of Qulipta for episodic migraine is 10 mg, 30 mg, or 60 mg taken orally once daily. The recommended dosage of Qulipta for chronic migraine is 60 mg taken once daily (2).

The recommended dose of Ubrelvy is 50 mg or 100 mg taken orally, as needed. If needed, a second dose may be administered at least 2 hours after the initial dose. The maximum dose in a



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24-hour period is 200 mg. The safety of treating more than 8 migraines in a 30-day period has not been established (1).

The American Academy of Neurology and the American Headache Society Position Statement recommends giving at least 2 conventional oral migraine preventive treatments an adequate trial of at least 6 weeks at a target or usual effective dose prior to initiating preventive therapy with a CGRP medication (5).

The safety and effectiveness of Nurtec ODT, Qulipta, and Ubrelvy in pediatric patients less than 18 years of age have not been established (1-3).

Summary

Nurtec ODT (rimegepant), Qulipta (atogepant), and Ubrelvy (ubrogepant) are calcitonin generelated peptide receptor (CGRP) antagonists. CGRP is a neuropeptide widely distributed in the nervous system, particularly at anatomical areas thought to be involved with migraine, including the trigeminovascular nociceptive system. In studies, CGRP has been shown to be released during severe migraine attacks. CGRP mechanism blockade either by small molecule receptor antagonists or by monoclonal antibodies can have an abortive or preventive effect in migraine. Nurtec ODT and Ubrelvy are indicated for the acute treatment of migraine with or without aura in adults. Nurtec ODT is indicated for the preventative treatment of episodic migraine in adults, while Qulipta is indicated for the preventative treatment of migraine in adults. The safety and effectiveness of Nurtec ODT, Qulipta, and Ubrelvy in pediatric patients less than 18 years of age have not been established (1-3).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of CGRP antagonists oral while maintaining optimal therapeutic outcomes.

References

- 1. Ubrelvy [package insert]. Madison, NJ: Allergan USA, Inc.; June 2023.
- 2. Qulipta [package insert]. Dublin, Ireland. Forest Laboratories Ireland Ltd.; June 2023.



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- 3. Nurtec ODT [package insert]. New Haven, CT: Biohaven Pharmaceuticals Inc.; April 2023.
- Karsan N, Goadsby PJ. "Calcitonin gene-related peptide and migraine." Curr Opin Neurol. 2015 Jun;28(3):250-4.
- (2019), The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache: The Journal of Head and Face Pain, 59: 1-18. https://doi.org/10.1111/head.13456