# Drug Monograph

Drug Name: **Nurtec™ (rimegepant) ODT Tablets**
Drug Class: **Alternative Oral Anti-Migraine Agents**
Prepared For: MO HealthNet
Prepared By: Conduent

☒ **New Criteria** ☐ **Revision of Existing Criteria**

## Executive Summary

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|---|---|
| **Purpose:** | The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, require a clinical edit or require prior authorization for use. |
| **Dosage Forms:** | Nurtec ODT is available as 75 mg orally disintegrating tablets in 8 count blister packs. |
| **Manufacturer:** | Manufactured for: Biohaven Pharmaceuticals, Inc., New Haven, CT 06510. |
| **Summary of Findings:** | Nurtec ODT is a calcitonin gene-related peptide receptor antagonist and is indicated for the acute treatment of migraine with or without aura in adults. In a randomized, double-blind, placebo-controlled study (N=1466) Nurtec ODT showed a statistically significant improvement in patients achieving headache pain freedom and most bothersome symptom (MBS) freedom two hours after a single dose compared to those who received placebo. The most common adverse reaction during the study was nausea. |

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|---|---|---|
| **Status Recommendation:** | ☐ Clinical Edit | ☐ PA Required |
| | ☐ Open Access | ☒ PDL |
| **Type of PA Criteria:** | ☐ Appropriate Indications | ☐ Non-Preferred |
| | ☐ No PA Required | ☒ Under Solicitation |

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## Purpose

The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug, a clinical edit drug or an open access drug. While prescription expenditures are increasing at double-digit rates, payers are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

## Introduction [1,2]

Migraine is a neurological disease that affects as many as 1 in 4 U.S. households and this widespread disease rank 6$^{th}$ in the world for the most disabling illness. While migraine affects women more than men, 18% to 6% respectively, it is still labeled as the 3$^{rd}$ most prevalent disease in the world and is estimated to affect nearly 39 million people in the U.S. alone. A migraine attack is more than just a headache and can present with nausea, vomiting, visual impairments, sensitivity to light and sound to name a few. One treatment option for migraine sufferers is to prevent a migraine using medications prophylactically. There are several prophylactic treatment options available with the newest form being calcitonin gene-related peptide (CGRP) inhibitors. This class of medication act to block the vasodilating CGRP neuropeptide believed to be vital to migraine presentation. To date there are a total of five CGRP inhibitors on the market. Nurtec ODT is the first oral treatment preparation as the other four products are dosed through subcutaneous injection or IV infusion and are indicated for prophylactic use.

## Dosage Form [1]

Nurtec ODT is available as 75 mg orally disintegrating tablets in 8 count blister packs.

## Manufacturer [1]

Manufactured for: Biohaven Pharmaceuticals, Inc., New Haven, CT 06510.

## Indication(s) [1]

Nurtec ODT is indicated for the acute treatment of migraine with or without aura in adults.

## Clinical Efficacy [1,2] (mechanism of action/pharmacology, comparative efficacy)

Nurtec ODT is a calcitonin gene-related peptide receptor antagonist. The CGRP is a strong vasodilator and is thought to be a key neuropeptide in migraine pathophysiology.

Pharmacokinetics:

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|---|---|
| **Volume of Distribution** | 120 L |
| **Metabolism** | Primarily CYP3A4 and lesser extent CYP2C9. |
| **Time to Peak** | 1.5 hours, delayed 1 hour with high fat meal |
| **Excretion** | Primarily unchanged feces (42%) and urine (51%) |
| **Half-life** | ~11 Hours |

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Clinical Trials Experience

**"Trial in Adult Subjects with Acute Migraines"**

| | |
|---|---|
| **STUDY 1 DESIGN** | Randomized, double-blind, placebo-controlled study (N=1466). |
| **INCLUSION CRITERIA** | • Adult migraine patients with and without aura.<br>• Rescue medication (NSAID, acetaminophen, and/or antiemetic) was allowed 2 hours after the initial treatment. |
| **EXCLUSION CRITERIA** | • This study did not allow rescue medication such as triptans within 48 hours of initial treatment. |
| **TREATMENT REGIMEN** | Patients were randomized to receive 75 mg of Nurtec ODT (N=732) or placebo (N=734) and instructed to treat a migraine of moderate to severe headache pain intensity. The primary efficacy endpoint analyzed pain freedom and most bothersome symptom (MBS). Pain freedom was defined by a reduction of moderate or severe headache pain to no headache pain and MBS as the absence of the self-identified symptom such as photophobia, phonophobia, or nausea. |
| **RESULTS** | Nurtec ODT showed a statistically significant improvement in patients achieving headache pain freedom and MBS two hours after a single dose compared to those who received placebo (p=<0.001 and p=0.001 respectively). Nurtec ODT also showed statistically significant effects of additional efficacy endpoints of pain relief at 2 hours, sustained pain freedom 2-48 hours, used of rescue medication within 24 hours, and the percentage of patients reporting normal function at two hours after dosing (p=<0.001). |
| **SAFETY** | Discussed in the Adverse Effects section below. |

## Contraindications [1]

- Nurtec ODT is contraindicated in patients with a history of hypersensitivity reaction to rimegepant or any of its components.

## Warnings and Precautions [1]

- Nurtec ODT has a warning for hypersensitivity reactions. These reactions can occur days after administrations and include dyspnea and rash.

## Adverse Effects [1]

| Most common, ≥ 2% | Nurtec ODT % | Placebo % |
|---|---|---|
| Nausea | 2 | 0.4 |

## Drug Interactions [1,2]

- **CYP3A4 Inhibitors:** Concomitant administration of Nurtec ODT with strong and moderate inhibitors of CYP3A4 can result in an increase in rimegepant exposure and should be avoided.
- **CYP3A Inducers:** Concomitant administration of Nurtec ODT with strong and moderate inducers of CYP3A can result in a decrease in rimegepant exposure and should be avoided.
- **Transporters:** Nurtec ODT should be avoided with inhibitors of P-*g*p or BCRP efflux transporters as rimegepant is a substrate of these transporters and concomitant used can cause significant increase in rimegepant exposure.

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## Dosage and Administration [1,2]

The recommended dose of Nurtec ODT is 75 mg orally with a maximum daily dose in a 24-hour period being 75 mg. It is important to note the proper handling of the ODT tablet to patients. The tablets should be handled with dry hands, and taken immediately after opening the blister pack. The ODT may be placed on the tongue or under the tongue.

## Cost

| Generic Name | Brand Name | Manufacturer | Dose | Cost**/ Dose |
|---|---|---|---|---|
| Rimegepant | Nurtec | Biohaven | 75 mg | $106.25 |

** Wholesale Acquisition Cost

## Conclusion

Nurtec ODT is a calcitonin gene-related peptide receptor antagonist and is indicated for the acute treatment of migraine with or without aura in adults. In a randomized, double-blind, placebo-controlled study (N=1466) Nurtec ODT showed a statistically significant improvement in patients achieving headache pain freedom and MBS freedom two hours after a single dose compared to those who received placebo. The most common adverse reaction during the study was nausea. Patients should be monitored for signs and symptoms of hypersensitivity reactions while using this medication and it is important to note the proper handling of the ODT tablet to patients.

## Recommendation

This drug is being considered for inclusion in the state specific Preferred Drug List (PDL).

## References


1) Product Information: Nurtec™ (rimegepant) ODT Tablets Biohaven Pharmaceuticals, Inc., New Haven, CT 06510.
2) Jasvinder, Chawla MD, Helmi, Lutsep MD et al. Migraine Headache February 28, 2020 Medscape.



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