Clinical Policy: Rimegepant (Nurtec ODT)

Reference Number: CP.PHAR.490
Effective Date: 09.01.20
Last Review Date: 08.20 Revision Log
Line of Business: Commercial, HIM, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Rimegepant (Nurtec® [orally disintegrating tablet] ODT) is a calcitonin gene-related peptide receptor (CGRP) antagonist.

FDA Approved Indication(s)

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

Limitation(s) of use: Nurtec ODT is not indicated for the preventive treatment of migraine.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Nurtec ODT is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Migraine (must meet all)**:**

1. Diagnosis of migraine headache;
2. Age ≥ 18 years;
3. Failure of at least TWO formulary $5HT_{1B/1D}$-agonist migraine medications* (e.g., sumatriptan, rizatriptan, zolmitriptan) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
   **Prior authorization may be required.*
4. For dose increase requests to quantities > 1 box of 8 ODTs per month, member meets all of the following (a, b, and c):
   a. Failure of at least TWO oral migraine prophylactic therapies from different therapeutic classes, each for 8 weeks, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*);
      **Prior authorization may be required.*
   b. Failure of a 3-month trial of ONE CGRP inhibitor* used for migraine prophylaxis, unless clinically significant adverse effects are experienced or all are contraindicated *(see Appendix B);*
      **Prior authorization may be required.*
   c. Member is being treated by or in consultation with a neurologist or headache/pain specialist;
5. Nurtec ODT is not prescribed concurrently with other CGRP inhibitors (e.g., Ubrelvy®, Aimovig®, Ajovy®, Emgality®);

6. Dose does not exceed 75 mg (1 ODT) per day for 15 days per month.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Migraine (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. For dose increase requests to quantities > 1 box of 8 ODTs per month, member meets all of the following (a, b, and c):
   a. Failure of at least TWO oral migraine prophylactic therapies from different therapeutic classes, each for 8 weeks, unless clinically significant adverse effects are experienced or all are contraindicated (*see Appendix B*);
      **Prior authorization may be required.*
   b. Failure of a 3-month trial of ONE CGRP inhibitor* used for migraine prophylaxis, unless clinically significant adverse effects are experienced or all are contraindicated *(see Appendix B);*
      **Prior authorization may be required.*
   c. Member is being treated by or in consultation with a neurologist or headache/pain specialist;
4. Nurtec ODT is not prescribed concurrently with other CGRP inhibitors (e.g., Ubrelvy, Aimovig, Ajovy, Emgality);
5. If request is for a dose increase, new dose does not exceed 75 mg (1 ODT) per day for 15 days per month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

5-HT: serotonin
AAN: American Academy of Neurology
AHS: American Headache Society
CGRP: calcitonin gene-related peptide
FDA: Food and Drug Administration
ODT: orally disintegrating tablet

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Abortive Migraine Therapy		
Drug Name	**Dosing Regimen**	**Dose Limit/Maximum Dose**
Triptans		
naratriptan (Amerge®)	One tablet (1 or 2.5 mg) PO at onset; can be repeated in 4 hours	5 mg/day
almotriptan (Axert®)	6.25 to 12.5 mg PO QD May repeat dose in 2 hours	25 mg/day
frovatriptan (Frova®)	2.5 mg PO QD May repeat dose in 2 hours	7.5 mg/day
sumatriptan (Imitrex® nasal spray)	One spray (5 to 20 mg) at onset into one nostril; can be repeated in 2 hours	40 mg/day
sumatriptan (Imitrex®)	One tablet (25 to 100 mg) PO at onset; can be repeated in two hours	200 mg/day
rizatriptan (Maxalt® /Maxalt MLT®)	One tablet (5 or 10 mg) PO at onset of migraine headache; can be repeated in two hours	30 mg/day
eletriptan (Relpax®)	20 or 40 mg PO QD May repeat dose in 2 hours	40 mg/dose 80 mg/day
zolmitriptan (Zomig®/Zomig® ZMT)	1.25 or 2.5 mg PO QD May repeat dose in 2 hours	5 mg/dose 10 mg/day

Prophylactic Migraine Therapy		
Drug Name	**Dosing Regimen**	**Level of Evidence***
Antiepileptic Drugs*		
divalproex sodium (Depakote®)	500 to 1,000 mg/day PO	Level A (AAN; AHS)
divalproex sodium ER (Depakote® ER)	500 to 1,000 mg/day PO	Level A (AAN; AHS)
topiramate (Topamax®)	100 mg/day PO	Level A (AAN; AHS)
Beta-Blockers		
metoprolol (Lopressor®)	200 mg/day PO	Level A (AAN; AHS)

Prophylactic Migraine Therapy		
Drug Name	**Dosing Regimen**	**Level of Evidence***
propranolol (Inderal®)	80 to 240 mg/day PO	Level A (AAN; AHS)
timolol (Blocadren®)	20 to 30 mg/day PO	Level A (AAN; AHS)
atenolol (Tenormin®)	100 mg/day PO	Level B (AAN; AHS)
nadolol (Corgard®)	80 to 240 mg/day PO	Level B (AAN; AHS)
Serotonin Reuptake Inhibitors		
venlafaxine XR (Effexor XR®)	150 mg/day PO	Level B (AAN; AHS)
Tricyclic Antidepressants		
amitriptyline (Elavil®)	30 to 150 mg/day PO	Level B (AAN; AHS)
CGRP Inhibitors*		
Aimovig (erenumab)	70 mg SC once a month; may be increased to 140 mg SC once a month	140 mg/month
Ajovy (fremanezumab)	225 mg SC once a month or 675 mg SC every 3 months	225 mg/month or 675 mg/3 months
Emgality (galcanezumab)	240 mg SC as a single loading dose, followed by 120 mg SC once a month	120 mg/month

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**American Headache Society (AHS) 2018, American Academy of Neurology (AAN) 2012: Level A: established efficacy, Level B: probably effective.*
***FDA approved.*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): history of hypersensitivity reaction to rimegepant, Nurtec ODT, or to any of its components.
- Boxed warning(s): none reported

Appendix D: General Information

The American Headache Society (2018) provides the following migraine guidance:

- Migraine patients who need to use acute treatments on a regular basis should be instructed to limit treatment to an average of 2 headache days per week, and patients observed to be exceeding this limit should be offered preventive treatment.
  Indications for preventive treatment:
  - Attacks significantly interfere with patients' daily routines despite acute treatment
  - Frequent attacks (≥ 4 migraine headache days [per month])
  - Contraindication to, failure, or overuse of acute treatments, with overuse defined as:
    - 10 or more days per month for ergot derivatives, triptans, opioids, combination analgesics, and a combination of drugs from different classes that are not individually overused
    - 15 or more days per month for non-opioid analgesics, acetaminophen, and nonsteroidal antiinflammatory drugs (NSAIDs [including aspirin])
    - Adverse effects with acute treatments

- Patient preference
- Prevention should also be considered in the management of certain uncommon migraine subtypes, including hemiplegic migraine, migraine with brainstem aura, migraine with prolonged aura, and those who have previously experienced a migrainous infarction, even if there is low attack frequency.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Migraine - acute treatment	75 mg PO as needed. The maximum dose in a 24-hour period is 75 mg. The safety of treating more than 15 migraines in a 30-day period has not been established.	75 mg/day

VI. Product Availability

ODT (blister pack of 8): 75 mg

VII. References

1. Nurtec ODT Prescribing Information. New Haven, CT: Biohaven Pharmaceuticals, Inc.; February 2020. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212728s000lbl.pdf. Accessed March 12, 2020.
2. Croop R, Goadsby PJ, Stock DA, et al. Efficacy, safety, and tolerability of rimegepant orally disintegrating tablet for the acute treatment of migraine: a randomised, phase 3, double-blind, placebo-controlled trial. The Lancet. August 31, 2019; 394:737-745.
3. MICROMEDEX® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 27, 2020.
4. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18.
5. Silberstein SD, Holland S, Freitag F, Dodick DW, Argoff C, Ashman E. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012;78:1337-1345.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.14.20	08.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.