Clinical Policy: Rimegepant (Nurtec ODT)

Reference Number: MDN.CP.PHAR.490
Effective Date: 04.01.22
Last Review Date: 5.15.23
Line of Business: Illinois Medicaid

Revision Log

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
- Preventive treatment of episodic migraine in adults.

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. Acute Migraine Treatment (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) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
4. For dose increase requests to quantities > 1 box of 8 ODTs per month, member must meet criteria in *Section I, B* below for migraine prophylaxis;
5. Dose does not exceed 75 mg (1 ODT) per day (one blister pack per month).

Approval duration: 6 months

B. Migraine Prophylaxis (must meet all)**:**

1. Diagnosis of episodic migraine;
2. Member experiences ≥ 4 migraine days per month for at least 3 months;
3. Member does not have chronic migraine, defined as ≥ 15 headache days/month with ≥ 8 migraine days/month for at least 3 months;
4. Prescribed by or in consultation with a neurologist, headache, or pain specialist;
5. Age ≥ 18 years;
6. Failure of at least 2 of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless clinically significant adverse

effects are experienced or all are contraindicated: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine);

7. If currently receiving treatment with Botox® for migraine prophylaxis and request is for concurrent use of Botox and Nurtec ODT (i.e., not switching from one agent to another), all of the following (a, b, and c):
   a. Sufficient evidence is provided from at least two high-quality*, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (i – iv):
      **Case studies or chart reviews are not considered high-quality evidence*
      i. Adequate representation of the member's clinical characteristics, age, and diagnosis;
      ii. Adequate representation of the prescribed drug regimen;
      iii. Clinically meaningful outcomes such as a reduction in monthly migraine or headache days;
      iv. Appropriate experimental design and method to address research questions (*see Appendix E for additional information*);
   b. Member has experienced and maintained positive response to Botox monotherapy as evidenced by a ≥ 30% reduction in migraine days per month from baseline following at least 2 quarterly injection (6 months) of Botox monotherapy;
   c. Despite Botox monotherapy, member continues to experience ≥ 4 migraine days per month and/or severe migraine headaches that result in disability and functional impairment;
8. Dose does not exceed 75 mg (1 ODT) every other day (two blister packs per month).

Approval duration: 6 months

C. Other diagnoses/indications

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*

2. Member is responding positively to therapy;
3. For dose increase requests to quantities > 1 box of 8 ODTs per month, member must meet criteria in *Section I, B* above for migraine prophylaxis;
4. If request is for a dose increase, new dose does not exceed 75 mg (1 ODT) per day (one blister pack per month)

Approval duration: 12 months

B. Migraine Prophylaxis (must meet all)**:**

1. Member meets one of the following (a or b):
   c. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   d. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. receiving medication via Centene benefit or member has previously met initial approval criteria;
3. Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month from baseline;
4. If request is for a dose increase, new dose does not exceed 75 mg (1 ODT) every other day (two blister packs per month).

Approval duration: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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.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		
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
Prophylactic Migraine Therapy		
Drug Name	**Dosing Regimen**	**Dose Limit/Maximum Dose**
Anticonvulsants such as: divalproex (Depakote®), topiramate (Topamax®), valproate sodium	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Beta-blockers such as: propranolol (Inderal®), metoprolol (Lopressor®)*, timolol, atenolol (Tenormin®)*, nadolol (Corgard®)*	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Antidepressants/tricyclic antidepressants* such as: amitriptyline (Elavil®), venlafaxine (Effexor®)	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*

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.

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.

Appendix E: Appropriate Experimental Design Methods

- Randomized, prospective controlled trials are generally considered the gold standard; however:
  - In some clinical studies, it may be unnecessary or not feasible to use randomization, double-blind trials, placebos, or crossover.
  - Non-randomized prospective clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- Case reports and chart reviews are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

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
Migraine prophylaxis	75 mg PO every other day	75 mg/dose

VI. Product Availability

ODT (blister pack of 8): 75 mg

VII. References

1. Nurtec ODT Prescribing Information. New Haven, CT: Biohaven Pharmaceuticals, Inc.; April 2022. Available at https://biohaven-nurtec-consumer-assets.s3.amazonaws.com/nurtec-prescribing-information.pdf. Accessed July 27, 2022.
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 July 27, 2022.
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.
6. Croop R, Lipton RB, Kudrow D, et al. Oral rimegepant for preventive treatment of migraine: a phase 2/3, randomised, double-blind, placebo-controlled trial. Lancet 2021; 397: 51–60.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created, adapted from CP.PHAR.490 to align with HFS PDL requirements	3.18.22	04.22
2Q 2022 annual review: Added criteria for concurrent use with Botox requiring supportive evidence from published studies or clinical practice guidelines, positive response with Botox monotherapy, and continued migraine burden; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	5.15.23	

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.