Clinical Policy: Rimegepant (Nurtec ODT)

Reference Number: ERX.SPA.398
Effective Date: 09.01.20
Last Review Date: 02.22
Line of Business: Commercial, 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 (CGRP) receptor 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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, 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 must meet criteria in *Section I.B* below for migraine prophylaxis;
5. Nurtec ODT is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Qulipta™, Ubrelvy®, Vyepti™);
6. 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. Failure of Qulipta (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced;
8. Nurtec ODT is not prescribed concurrently with Botox® or other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality, Qulipta, Ubrelvy, Vyepti);
9. Dose does not exceed 75 mg (1 ODT) every other day (two blister packs per month).

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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 must meet criteria in *Section I.B* above for migraine prophylaxis;
4. Nurtec ODT is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality, Qulipta, Ubrelvy, Vyepti);
5. 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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month from baseline;
3. Nurtec ODT is not prescribed concurrently with Botox® or other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality, Qulipta, Ubrelvy, Vyepti);*
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: 6 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 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	**Dosage 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*
Qulipta™ (atogepant)	10 mg, 30 mg, or 60 mg PO QD	60 mg/day

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.

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.; May 2021. Available at https://biohaven-nurtec-consumer-assets.s3.amazonaws.com/nurtec-prescribing-information.pdf. Accessed September 15, 2021.
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 March 30, 2021.
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	04.14.20	08.20
3Q 2021 annual review: RT4 added new indication for episodic migraine prophylaxis; references reviewed and updated.	06.28.21	08.21
1Q 2022 annual review: per SDC and prior clinical guidance for migraine prophylaxis added redirection to newly approved oral CGRP Qulipta; references reviewed and updated.	11.17.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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