Clinical Policy Title:	rimegepant
Policy Number:	RxA.717
Drug(s) Applied:	Nurtec® ODT
Original Policy Date:	12/07/2021
Last Review Date:	12/07/2021
Line of Business Policy Applies to:	All lines of business

Background

Rimegepant (Nurtec® ODT) is a calcitonin gene-related peptide receptor antagonist indicated for the:

- Acute treatment of migraine with or without aura in adults.
- Preventive treatment of episodic migraine in adults.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
rimegepant (Nurtec® ODT)	Acute treatment of migraine with or without aura in adults	Recommended dose: 75 mg orally, as needed	75 mg/day orally
	Preventive treatment of episodic migraine	Recommended dose: 75 mg orally every other day	75 mg orally every other day

Dosage Forms

- Nurtec® orally disintegrating tablets: 75 mg.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Episodic migraine prophylaxis (must meet all)**:**

1. Diagnosis of episodic migraine;
2. Age ≥ 18 years;
3. Member must experience a or b:
    a. at least 4 headaches per month or;
    b. at least 8 headache days per month;
4. Failure of an 8 week trial at least two (2) of the following oral migraine preventative therapies, each from a different class, unless contraindicated or clinically significant adverse effects are experienced (a, b, or c):

a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate);
b. beta-blockers (e.g., metoprolol, propranolol, timolol);
c. antidepressants (e.g., amitriptyline, venlafaxine);

5. Member does not have a history of cardiovascular disease (hypertension, ischemic heart disease), neurological disease, or cerebrovascular disease;
6. Requested dose does not exceed 75 mg orally every other day.

Approval Duration
Commercial: 3 months
Medicaid: 3 months

B. Acute treatment of migraine with or without aura (must meet all)**:**

1. Diagnosis acute migraine with or without aura;
2. Prescribed by or in consultation with a neurologist, pain specialist or headache specialist;
3. Age ≥ 18 years;
4. Member experiences between 4 and 14 headache days per month;
5. Failure of at least two (2) triptans (e.g., eletriptan, rizatriptan, sumatriptan) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Member must currently be treated with one of the following preventative treatments, unless previously ineffective, contraindicated, or clinically significant adverse effects are experienced (a, b, or c):
    a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate);
    b. beta-blockers (e.g., metoprolol, propranolol, timolol);
    c. antidepressants (e.g., amitriptyline, venlafaxine);
7. Requested dose does not exceed 75 mg orally once daily.

Approval Duration
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

A. Episodic migraine prophylaxis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy and meets both of the following (a and b):
    a. Reduction in monthly headache days by at least 2 days;
    b. Improvement in migraine-related disability;
3. If request is for a dose increase, new dose does not exceed 75 mg orally every other day;

Approval Duration
Commercial: 6 months
Medicaid: 6 months

B. Acute treatment of migraine with or without aura (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 75 mg orally once daily;

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
CGRP: calcitonin gene-related peptide

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Anticonvulsants		
divalproex (Depakote®)	250 mg orally twice daily initially. Titrate as needed up to a maximum of 500 mg orally twice daily.	1,000 mg/day
topiramate (Topamax®)	25 mg orally every evening for 1 week, then 25 mg orally twice daily for 1 week, then 25 mg orally every morning and 50 mg orally every evening for 1 week, and then 50 mg orally twice daily	100 mg/day
Beta-blockers		
propranolol	Initially, 80 mg/day orally given in divided doses. May gradually increase dosage if needed to 160 to 240 mg/day. Doses of 40 to 320 mg/day orally	240 mg/day
metoprolol (Lopressor®)	Initially, 25 mg orally twice daily. Titrate to response; up to 200 mg/day orally in divided doses	400 mg/day
timolol	Initially, 10 mg orally twice daily. May give maintenance dose of 20 mg orally once daily. Dosage range: 10 to 30 mg/day orally. Discontinue treatment after 8 weeks if maximum dosage is ineffective.	30 mg/day
Antidepressants/tricyclic antidepressants*		
amitriptyline	25 mg orally once daily at bedtime, initially; titrate as tolerated to efficacy. Usual effective target dose range: 75 to 100 mg orally once daily	150 mg/day orally in outpatients; 300 mg/day orally for hospitalized patients.
venlafaxine	37.5 mg orally once daily for 3 days, then 75 mg orally once daily for 3 days, followed by 150 mg orally once daily	225 mg/day orally is maximum recommended for outpatients; up to 375 mg/day orally for hospitalized inpatients.

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by

generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Patients with a history of hypersensitivity reaction to rimegepant, Nurtec® ODT, or to any of its components.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Strong CYP3A4 Inhibitors, Inhibitors of P-gp or BCRP, Strong and Moderate CYP3A Inducers: Avoid concomitant administration.
- Moderate CYP3A4 Inhibitors: Avoid another dose within 48 hours when administered with a moderate CYP3A4 inhibitor.

References

1. Nurtec® ODT. Prescribing Information. New Haven, CT: Biohaven Pharmaceuticals Inc; May 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212728s006lbl.pdf. Accessed October 25, 2021.
2. Clinical Pharmacology. Tampa, FL: Elsevier, 2020. Available at: https://www.clinicalkey.com. Accessed October 25, 2021.
3. IPD Analytics Rx Insights_New Drug Approval Review_ Nurtec _25 2021. Accessed with subscription at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Nurtec+ODT.Accessed October 25, 2021.
4. Nurtec® ODT. Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed October 25, 2021.
5. Ha H, Gonzalez A. Migraine headache prophylaxis. AFP. 2019;99(1):17-24. Available at: https://www.aafp.org/afp/2019/0101/p17.html#afp20190101p017-b4 Accessed October 29, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	10/26/2021	12/07/2021