Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 08/01/2020**
Policy Number: PA.CP.PHAR.490	**Effective Date: 07/15//2020** **Revision Date: 07/15/2020**
Policy Name: Rimegepant (Nurtec ODT)	

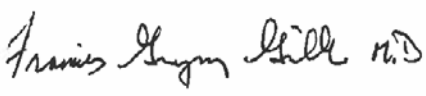
Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy Created

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Rimegepant (Nurtec ODT)

Reference Number: PA.CP.PHAR.490
Effective Date: 07/2020
Last Review Date: 07/2020 Revision Log

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 PA Health & Wellness® 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 requests for quantities greater than 8 ODTs per month, member meets one of the following (a or b):
   a. Failure of TWO prophylactic migraine medications, unless clinically significant adverse effects are experienced or all are contraindicated *(see Appendix B)*;
   b. Member is being treated by or in consultation with a neurologist or a headache 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 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. For requests for quantities greater than 8 ODTs per month, member meets one of the following (a or b):
   a. Failure of TWO prophylactic migraine medications, unless clinically significant adverse effects are experienced or all are contraindicated *(see Appendix B)*;
   b. Member is being treated by or in consultation with a neurologist or a headache 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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

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	25 mg/day

	May repeat dose in 2 hours	
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)
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	07/2020	