DRUG DETERMINATION POLICY

Title: DDP-47 CGRP Antagonists

Effective Date: 12/28/2021



Physicians Health Plan PHP Insurance Company PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

- 1. The terms of the applicable benefit document in effect on the date of service.
- 2. Any applicable laws and regulations.
- 3. Any relevant collateral source materials including coverage policies.
- 4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

CGRP (calcitonin gene-related peptide) antagonists (Nurtec, Ubrelvy, Aimovig, Ajovy, Emgality and Vyepti) are agents used to treat and prevent migraine. These criteria were developed and implemented to ensure appropriate use for the intended severity of condition and use of conventional treatment prior these agents.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

- I. Abortive treatment of migraines [must meet all listed below]:
 - A. Age: at least 18 years.
 - B. Diagnosis and severity [must meet both listed below]:
 - 1. Diagnosis: migraine headache.
 - 2. Frequency: at least four migraines per month.
 - C. Other therapies: contraindication, inadequate response after four months or significant adverse effects to one abortive and one preventive agent as listed below:
 - 1. Abortive: generic triptans (e.g., almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan).

- 2. Preventive: beta blocker, anticonvulsant (e.g., valproic acid derivative, topiramate), antidepressant (e.g., amitriptyline, venlafaxine).
- C. Dosage regimen and quantity limits.
 - 1. Nurtec (rimegepant):
 - a. Dosage: 75mg as a single dose (maximum dose 75mg per 24 hours).
 - b. Quantity limit: eight per month.
- D. Approval.
 - 1. Initial approval: six months.
 - 2. Re-approval: one year; must document decrease in severity and duration of migraines.
- II. Prevention of migraines [must meet all listed below]:
 - A. Age: at least 18 years.
 - B. Diagnosis and severity [must meet one listed below]:
 - 1. Episodic migraine: at least four migraines per month.
 - 2. Chronic migraine: at least 15 migraine days per month.
 - 3. Cluster headache: at least one attach every other day up to eight attaches per day (only for Emgality).
 - C. Subcutaneous and oral agent other therapies: contraindication, inadequate response after four months or significant adverse effects to two preventive categories listed below:
 - 1. Beta blocker.
 - 2. Anticonvulsant (e.g. valproic acid derivative, topiramate).
 - 3. Antidepressant (e.g. amitriptyline, venlafaxine).
 - D. Intravenous agent other therapies: contraindication, inadequate response after four months or significant adverse effects to two preventive categories plus one subcutaneous CGRP listed below:
 - 1. Beta blocker.
 - 2. Anticonvulsant (e.g., valproic acid derivative, topiramate).
 - 3. Antidepressant (e.g., amitriptyline, venlafaxine).
 - 4. Subcutaneous CGRP: Aimovig, Ajovy, Emgality.
 - E. Dosage regimen.
 - 1. Aimovig subcutaneous (erenumab SQ): 70mg per month; may increase to 140mg if inadequate response.

- 2. Ajovy subcutaneous (fremanezumab SQ): 225mg per month or 675mg every three months.
- 3. Emgality subcutaneous (galcanezumab SQ):
 - a. Migraine: 240mg single loading dose, then 120mg per month.
 - b. Cluster headache: 300mg at onset of cluster period and once monthly until end of the cluster period.
- 4. Nurtec oral (rimegepant): 75mg every other day.
- 5. Vyepti intravenous (eptinezumab IV): 100mg every three months.
- E. Approval.
 - 1. Initial approval: six months.
 - 2. Re-approval: one year; must demonstrate reduction in either number of migraines per month or 50 percent reduction in cluster headaches per week.

III. Exclusions.

- A. Excluded agents: Ubrevly (ubrogepant).
 - 1. All preferred migraine agents, contraindicated, inadequate response or significant adverse events.

4.0 Coding:

None.

5.0 Appendices:

See page 5.

6.0 References, Citations & Resources:

- 1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Nurtec, Aimovig, Ajovy, Emgality accessed August 2021.
- 2. UpToDate: Preventive treatment of migraines in adults accessed September 2020, <u>https://www.uptodate.com/contents/preventive-treatment-of-migraine-in-</u> <u>adults?search=cgrp%20antagonist&source=search_result&selectedTitle=2~12&usage_type=defa</u> <u>ult&display_rank=1</u>.
- UpToDate: Acute treatment of migraine in adults assessed September 2020, https://www.uptodate.com/contents/acute-treatment-of-migraine-inadults?search=cgrp%20antagonist&source=search_result&selectedTitle=3~12&usage_type=defa ult&display_rank=2.
- 4. UpToDate: Chronic migraine assessed September 2020, <u>https://www.uptodate.com/contents/chronic-</u> <u>migraine?search=cgrp%20antagonist&source=search_result&selectedTitle=4~12&usage_type=d</u> <u>efault&display_rank=3</u>.

7.0 Revision History:

Original Effective Date: 11/30/2020

Next Review Date: 05/25/2022

Revision Date	Reason for Revision	
1/21	Off cycle review, excluded Ubrevly, removed abortive other therapies from 3.0.II,	
	added Nurtec to purpose	
5/21	Annual review; no changes	
7/21	Off cycle review; added dosage and quantity limit for Nurtec	
10/21	Off cycle review; added Vyepti	

Appendix I - Monitoring and patient safety

Drug	Adverse Reactions	Monitoring	REMS
Nurtec	 Central Nervous System: drowsiness	• NA	None
(Rimegepant)	(Ubrevly: 2-3%) Gastrointestinal: nausea (2%-4%)		needed
Aimovig SQ (erenumab) Ajovy SQ (fremanezumab) Emgality SQ (galcanezumab)	 Gastrointestinal: constipation (Aimojig: 3%) Immunologic antibody development (3-6%) Local: injection site reaction (Aimovig: 5-6%; Ajovy: 43-45%) Neuromuscular and Skeletal: muscle cramps /spasms (2%) 	 Cardiovascular: blood pressure Central Nervous System: number of monthly migraine days 	None needed
Vyepti IV	 Immunological: antibody development	• NA	None
(eptinezumab)	(18-21%, neutralizing (35-41%)		needed