Washington State Health Care Authority

# Antivirals: HIV – rilpivirine (Edurant®)

## Medical policy no. 12.10.90.AA Effective Date: TBD

**Related medical policies:**

- **12.10.99 Antivirals- HIV Combinations**
- **12.10.99.AA Antivirals- HIV: emtricitabine alafenamide-tenofovir (Descovy)**
- **12.10.99.AB Antivirals: HIV- cabotegravir/rilpivirine (Cabenuva)**

***Note:*** *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least ONE preferred regimen. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

*To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx*

## Background:

Human immunodeficiency virus (HIV) is a single-stranded RNA retrovirus that attacks the immune system, specifically CD4+ T-helper cells, causing a progressive decrease in CD4+ T cell count and increased susceptibility of a person to infections. If left untreated, HIV can lead to acquired immunodeficiency syndrome (AIDS) which is the most severe phase of HIV infection. Approximately 1.1 million people in the U.S. live with HIV and about 14% of those living with HIV are unaware of their status. Although no cure for HIV currently exists, the use of antiretroviral therapy (ART) can help suppress the HIV virus and stop progression of the disease. ART therapy is recommended for all patients diagnosed with HIV to help protect the immune system and reduce the risk of serious health complications.

## Medical necessity

| Drug | Medical Necessity |
|---|---|
| Rilpivirine (Edurant®) | Rilpivirine may be considered medically necessary for the following indications:<br>• Treatment of HIV-1 infection in patients<br>• In combination with cabotegravir for short-term treatment to replace current stable antiviral regimen |

## Clinical policy:

| Clinical Criteria | |
|---|---|
| **HIV-1 Infection** | Rilpivirine may be authorized when **ALL** of the following are met:<br>1. Patient is treatment naïve and meets **ALL** the following (a-d):<br>a. Confirmed diagnosis of HIV-1**; AND**<br>b. HIV-1 RNA ≤ 100,000 copies/mL; **AND**<br>c. CD4 cell count greater than or equal to 200 cells/$mm^3$; **AND** |

| | |
|---|---|
| | **d.** Prescribed in combination with other appropriate antiretroviral agents; **AND**<br>2. Patient is antiretroviral therapy (ART) experienced with virologic suppression for at least 6 months (HIV-1 RNA < 50 copies/mL); **AND**<br>3. Patient is 12 years of age or older; **AND**<br>4. Body weight is greater than or equal to 35 kg; **AND**<br>5. Rilpivirine will not be co-administered with any of the following:<br>a. Carbamazepine<br>b. Dexamethasone (more than a single dose treatment)<br>c. Esomeprazole<br>d. Lansoprazole<br>e. Omeprazole<br>f. Oxcarbazepine<br>g. Pantoprazole<br>h. Phenobarbital<br>i. Phenytoin<br>j. Rabeprazole<br>k. Rifampin<br>l. Rifapentine<br>m. St. John's Wort<br><br>If ALL criteria are met, the request will be approved for **12 months**<br><br>If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration. |
| | **Criteria (Reauthorization)**<br>Rilpivirine may be reauthorized if the patient shows previous history of medication use within the last 6 months. The request will be approved for **12 months.**<br><br>If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration. |
| **In combination with cabotegravir for short-term treatment to replace current stable antiviral regimen** | Rilpivirine may be authorized when **ALL** of the following are met:<br>1. Patient is antiretroviral therapy (ART) experienced with virologic suppression for at least 6 months (HIV-1 RNA < 50 copies/mL); **AND**<br>2. Patient is 18 years of age or older; **AND**<br>3. Body weight is greater than or equal to 35 kg<br><br>If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis. |

## Dosage and quantity limits

| Drug Name | Dose and Quantity Limits |
|---|---|
| **Rilpivirine (Edurant®)** | • #30 for 30 day supply |

## References


1. Aboud M, Orkin C, Podzamczer D, et al. Efficacy and safety of dolutegravir–rilpivirine for maintenance of virological suppression in adults with HIV-1: 100-week data from the randomised, open-label, phase 3 SWORD-1 and SWORD-2 studies. The Lancet HIV. https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(19)30149-3/fulltext. Published September 1, 2019. Accessed April 28, 2021.
2. Edurant [package insert]. Titusville, NJ; Janssen; January 2021.


## History

| Date | Action and Summary of Changes |
|---|---|
| **04/07/2021** | New policy created |

Washington State Health Care Authority

# Antivirals: HIV – rilpivirine (Edurant®)

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

| Date of request: | Reference #: | MAS: | |
|---|---|---|---|
| Patient | Date of birth | ProviderOne ID | |
| Pharmacy name | Pharmacy NPI | Telephone number | Fax number |
| Prescriber | Prescriber NPI | Telephone number | Fax number |
| Medication and strength | Directions for use | Qty/Days supply | |

1. Is this request for a continuation of therapy? ☐ Yes ☐ No

2. Indicate patient's diagnosis:
   ☐ HIV-1 Treatment.
   Which other ART medication will be used in combination with rilpivirine (Edurant)?
   ☐ Other. Specify:

3. Will the patient be using rilpivirine (Edurant) in combination with cabotegravir? ☐ Yes ☐ No

4. Is patient treatment naïve? ☐ Yes ☐ No

5. HIV-1 RNA copies/mL

6. Has patient been adherent to an ART regimen in the last 6 months? ☐ Yes ☐ No

7. What is the patient's current weight? kg Date taken:

8. Will the patient be using any of the following medications? (check all that apply)
   ☐ Carbamazepine ☐ Dexamethasone (more than a single dose treatment)
   ☐ Oxcarbazepine ☐ Phenobarbital ☐ Phenytoin
   ☐ Rifampin ☐ Rifapentine ☐ St John's Wort
   ☐ Proton pump inhibitors (i.e. esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole)

**CHART NOTES, LABS and TESTS ARE REQUIRED WITH THIS REQUEST**

| Prescriber signature | Prescriber specialty | Date |
|---|---|---|