Antivirals: HIV– rilpivirine (Edurant®)

WA.PHAR.120 Antivirals HIV- rilpivirine (Edurant)

Effective Date: December 1, 2021

Related medical policies:

- **WA.PHAR.97- HIV Combinations**
- **WA.PHAR.98 - HIV: emtricitabine alafenamide-tenofovir (Descovy)**
- **WA.PHAR.119 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. 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 current publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit: https://pharmacy.envolvehealth.com/content/dam/centene/envolve-pharmacy-solutions/pdfs/PDL/FORMULARY-CoordinatedCare_Washington.pdf

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 in patients who meet the criteria described in the clinical policy below.

Clinical policy:

Clinical Criteria	
HIV-1 Infection	Rilpivirine may be authorized when **ALL** of the following are met: 1. Patient is antiretroviral therapy (ART) experienced with virologic suppression for at least 6 months (HIV-1 RNA < 50 copies/mL); **OR** 2. Patient is treatment naïve and meets **ALL** the following (a-c):

	a. Confirmed diagnosis of HIV-1**; AND** b. HIV-1 RNA ≤ 100,000 copies/mL; **AND** c. Prescribed in combination with other appropriate antiretroviral agents; **AND** 3. Patient is 12 years of age or older; **AND** 4. Body weight is greater than or equal to 35 kg; **AND** 5. Rilpivirine will not be co-administered with any of the following: a. Carbamazepine b. Dexamethasone (more than a single dose treatment) c. Esomeprazole d. Lansoprazole e. Omeprazole f. Oxcarbazepine g. Pantoprazole h. Phenobarbital i. Phenytoin j. Rabeprazole k. Rifampin l. Rifapentine m. St. John's Wort If ALL criteria are met, the request will be approved for **12 months** 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) 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.** 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: 1. Patient is antiretroviral therapy (ART) experienced with virologic suppression for at least 6 months (HIV-1 RNA < 50 copies/mL); **AND** 2. Patient is 18 years of age or older; **AND** 3. Body weight is greater than or equal to 35 kg If ALL criteria are met, the request will be approved for **12 months.** 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
06/16/2021	Approved by DUR Board
07/21/2021	Removed CD4 criteria to align with other HIV policies
10/25/2021	Removed statement from note section "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."