Prior Authorization DRUG Guidelines

**EDURANT (Rilpivirine)**

Effective Date: 1/28/14  
Date Developed: 1/28/14 by Catherine Sanders, MD  
Date Approved by P&T Committee: 1/26/16, 1/24/17, 1/23/18, 1/22/19

Edurant is an Antiretroviral Agent, Reverse Transcriptase Inhibitor (Non-nucleoside) used in the treatment of HIV-1 infections. Rilpivirine has activity against HIV-1 by binding to reverse transcriptase. It consequently blocks the RNA-dependent and DNA-dependent DNA polymerase activities, including HIV-1 replication. It does not require intracellular phosphorylation for antiviral activity.

**Pre-Authorization Criteria:**

- treatment of HIV-1 infections in antiretroviral treatment-naïve patients with HIV-1 RNA less than or equal to 100,000 copies/mL at the start of therapy

  Note: to be used in combination with at least 2 other antiretroviral agents.

  Note: VCHCP requires that Edurant be prescribed by an Immunology Clinic physician with current American Academy of HIV Medicine (AAHIVM) certification or a physician boarded in Infectious Disease.

  Note: not recommended for patients less than 18 years of age

**Dosing:**  
**Adult:**  
Treatment of HIV-1 infection: Oral: 25 mg once daily.

**Dosing:**  
**Pediatric:**  
Pediatric dosing is currently unavailable or not applicable

**Dosing:**  
**Renal Impairment:**  
Mild-to-moderate renal impairment: No dosage adjustment necessary.  
Severe or end-stage renal impairment: Use with caution; no dosage adjustment necessary (DHHS, 2012)

**Dosing:**  
**Hemodialysis/peritoneal dialysis:** Due to extensive protein binding, significant removal by hemodialysis or peritoneal dialysis is unlikely.

**Dosing:**  
**Hepatic Impairment:**  
Mild-to-moderate impairment (Child-Pugh class A or B): No dosage adjustment necessary.  
Severe impairment (Child-Pugh class C): No dosage adjustment provided in the manufacturer’s labeling (has not been studied); DHHS HIV guidelines also have no dosage recommendation (DHHS, 2012).
Dosage Forms: U.S.:
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.
Tablet, Oral:
Edurant: 25 mg

Generic Equivalent Available: U.S.-No

Administration:
Administer with a normal- to high-calorie meal. Taking with a protein supplement drink alone does not increase absorption.

Contraindications:
Current use of carbamazepine, dexamethasone (>1 dose), oxcarbazepine, phenobarbital, phenytoin, proton pump inhibitors (PPIs), rifabutin, rifampin, rifapentine, or St. John’s wort.

Adverse Reactions:
>10% - cholesterol increased, LDL increased, ALT increased, AST increased
Other Serious Less Common Reactions: Depression, suicidality, fat redistribution, hepatotoxicity, immune reconstitution syndrome, autoimmune disorders.

Exclusions:
Edurant is not for use in treatment-experienced patients.

References:


10. www.uptodate.com: Rilpivirine: Drug Information
11. www.epocrates.com: Edurant Drug Information

REVISION HISTORY:

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
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Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD
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