VENTURA COUNTY
HEALTH CARE PLAN

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, 2/18/20

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)
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, imjune reconstitution syndrome, autoimmune disorders.

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

References:

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2. Cohen CJ, Molina JM, Cahn P, et al, "Efficacy and Safety of Rilpivirine (TMC278) Versus Efavirenz at 48 Weeks in Treatment-Naive HIV-1-Infected Patients: Pooled Results from the Phase 3 Double-Blind Randomized ECHO and THRIVE Trials," *J Acquir Immune Defic Syndr*, 2012, 60(1):33-42. [PubMed 22343174]
3. Cohen CJ, Molina JM, Cassetti I, et al, "Week 96 Efficacy and Safety of Rilpivirine in Treatment-Naive HIV-1 Infected Patients in Two Phase II Randomized Trials," *AIDS*, 2013, 7(6):939-50. [PubMed 23211772]
4. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents, "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, Department of Health and Human Services," February 12, 2013;1-267. Available at http://www.aidsinfo.nih.gov
5. Fulco PP and McNicholl IR, "Etravirine and Rilpivirine: Nonnucleoside Reverse Transcriptase Inhibitors With Activity Against Human Immunodeficiency Virus Type 1 Strains Resistant to Previous Nonnucleoside Agents," *Pharmacotherapy*, 2009, 29(3):281-94. [PubMed 19249947]
6. MacArthur RD, "Clinical Trial Report: TMC278 (Rilpivirine) Versus Efavirenz as Initial Therapy in Treatment-Naïve, HIV-1-Infected Patients," *Curr Infect Dis Rep*, 2011, 13(1):1-3. [PubMed 21308448]
7. Molina JM, Clumeck N, Orkin C, et al, "Rilpivirine Efficacy, Virology and Safety in ARV Treatment-Naïve Patients With Viral Load ≤100,000 HIV-1 RNA c/mL: ECHO and THRIVE 96 Week Results," *J Int AIDS Soc*, 2012, 15(6):18250. [PubMed 23234922]

8. Nelson M, Amaya G, Clumeck N, et al, "Efficacy and Safety of Rilpivirine in Treatment-Naive HIV-1-Infected Patients With Hepatitis B Virus/Hepatitis C Virus Coinfection Enrolled in the Phase III Randomized, Double-Blind ECHO and THRIVE Trials," *J Antimicrob Chemother*, 2012, 67(8):2020-8. [PubMed 22532465]

9. Pozniak AL, Morales-Ramirez J, Katabira E, et al, "Efficacy and Safety of TMC278 in Antiretroviral-Naïve HIV-1 Patients: Week 96 Results of a Phase IIb Randomized Trial," *AIDS*, 2010, 24(1):55-65. [PubMed 19926964]
10. www.uptodate.com: Rilpivirine: Drug Information
11. www.epocrates.com: Edurant Drug Information

REVISION HISTORY:

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1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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