VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Isentress ® (raltegravir)

Effective Date: 1/31/12

Date Developed: 1/24/12 by Albert Reeves MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 7/23/19, 2/18/20, 2/2/21

(ARCHIVED 8/3/21)

Isentress ® (raltegravir) is an Antiretroviral Agent, Integrase Inhibitor

Pre-Authorization Criteria:

VCHCP will authorize Isentress (raltegravir for FDA indicated treatment of Treatment of HIV-1 infection in combination with other antiretroviral agents.

VCHCP requires that Isentress ® (raltegravir) be prescribed by an Infectious Disease Physician or Physician with current American Academy of HIV Medicine (AAHIVM) Certification except for post exposure prophylaxis (PEP). Primary Care Physicians (PCPs) can prescribe PEP.

Dosing: Adult

HIV treatment: Oral: 400 mg twice daily. **Note:** Recommended as a first-line therapy in combination with tenofovir/emtricitabine (Truvada) for PEP in antiretroviral naïve patients

Dosing: Pediatric

HIV Treatment: Adolescents ≥16 years: Refer to adult dosing.

Dosage Forms: U.S.

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Tablet, oral: Isentress®: 400 mg

Administration

May be administered without regard to meals.

Warnings/Precautions

Concerns related to adverse effects:

Immune reconstitution syndrome: Patients may develop immune reconstitution syndrome resulting in the occurrence of an inflammatory response to an indolent or residual opportunistic infection; further evaluation and treatment may be required.

Myopathy: Grade 2-4 creatine kinase (CK) increases have been observed and myopathy and rhabdomyolysis have been reported; use caution in patients with risk factors for CK elevations and/or skeletal muscle abnormalities, including taking other drugs known to cause myopathy or rhabdomyolysis.

DRUG Interactions

(For additional information: Launch Lexi-Interact™ Drug Interactions Program)

Efavirenz: May decrease the serum concentration of Raltegravir. *Risk C: Monitor therapy*

Fosamprenavir: Raltegravir may decrease the serum concentration of Fosamprenavir. Fosamprenavir may decrease the serum concentration of Raltegravir. *Risk D: Consider therapy modification*

Proton Pump Inhibitors: May increase the serum concentration of Raltegravir. *Risk C: Monitor therapy*

Rifampin: May decrease the serum concentration of Raltegravir. Management: Increase raltegravir dose to 800 mg twice daily (adult dose) when used concomitantly with rifampin. *Risk D: Consider therapy modification*

Tipranavir: May decrease the serum concentration of Raltegravir. *Risk C: Monitor therapy*

REFERENCES

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3. Lennox JL, DeJesus E, Lazzarin A, et al, "Safety and Efficacy of Raltegravir-Based versus Efavirenz-Based Combination Therapy in Treatment-Naive Patients with HIV-1 Infection: A Multicentre, Double-Blind Randomised Controlled Trial," *Lancet*, 2009, 374(9692):796-806. [PubMed 19647866]

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5. Panel on Antiretroviral Guidelines for Adults and Adolescents, "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents, Department of Health and Human Services," January 10, 2011; 1-166. Available at http://www.aidsinfo.nih.gov

6. "Perinatal HIV Guidelines Working Group. Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States," May 24, 2010. Available at http://aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf

7. Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children, "Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection," August 16, 2010. Available at http://www.aidsinfo.nih.gov

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
6/19/19	Yes	Howard Taekman, MD	Updated to allow PCPs to prescribe for PEP and **Note:** Recommended as a first-line therapy in combination with tenofovir/emtricitabine (Truvada) for PEP in antiretroviral naïve patients
2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
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