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

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
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

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Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/18/20

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<th>Content Revised (Yes/No)</th>
<th>Contributors</th>
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<td>1/24/17</td>
<td>No</td>
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<td>Updated to allow PCPs to prescribe for PEP and <strong>Note:</strong> Recommended as a first-line therapy in combination with tenofovir/emtricitabine (Truvada) for PEP in antiretroviral naïve patients</td>
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