VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Tivicay (dolutegravir)

Effective Date 1/24/17
Developed 12/29/16 by R. Sterling, MD
Last Approval Date: 1/24/17, 1/23/18, 1/22/19, 2/18/20

Dolutegravir is an HIV-1 antiviral agent that binds to the integrase active site and inhibits the strand transfer step of HIV-1 DNA integration necessary for HIV replication. Please note that the Institute for Safe Medication Practices (ISMP) includes dolutegravir among its list of drugs having a heightened risk of significant patient harm when used in error. Please also note that use is complicated by instances of INSTI (integrase strand transfer inhibitor) resistance.

Pre-authorization Criteria: Treatment of HIV-1 infection in combination with other antiretroviral agents in adult and pediatric patients weighing at least 30 kg who are treatment naïve or treatment-experienced but integrase strand transfer inhibitor (INSTI) naïve, or INSTI experienced with certain INSTI-associated resistance substitutions or clinically suspected INSTI resistance.

Off-Label use: HIV-1 non-occupational post-exposure prophylaxis (nPEP). Please see the VCHCP Coverage of Prescription Medication for Off-Label Use policy.

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

Dosing:

Treatment-naive or treatment-experienced integrase strand transfer inhibitor (INSTI)-naive*:* Oral: 50 mg once daily

Treatment-naive or treatment-experienced INSTI-naive when co-administered with carbamazepine, efavirenz, fosamprenavir/ritonavir, tipranavir/ritonavir, or rifampin: Oral: 50 mg twice daily (pediatric 30-40 kg: 35 mg)

INSTI-experienced with certain INSTI-associated resistance substitutions or clinically suspected INSTI resistance (**Note:** Consult prescribing information for details): Oral: 50 mg twice daily (pediatric 30-40 kg: 35 mg)

Off-Label Use: nPEP: Adults and adolescents weighing ≥40 kg: Oral: 50 mg once daily for 28 days in combination with other antiretroviral agents. Initiate therapy within 72 hours of exposure.

How Supplied: oral tablets 10, 25, 50 mg

Adverse Reactions/Precautions: abdominal pain, nausea, flatulence, pruritus, fatigue, headache, depression/insomnia; hypersensitivity reactions; has not been studied in patients with liver impairment

Drug Interactions: mineral salts (e.g. calcium, iron, zinc, selenium) decrease serum concentration; other drugs decrease serum concentration (see product literature)

REFERENCES:

HHS 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. Updated April 8, 2015.

HHS Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the use of antiretroviral agents in pediatric HIV infection. March 1, 2016.

HHS. Updated Guidelines for Antiretroviral Post exposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV - United States, 2016.

Tivicay (dolutegravir) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; June 2016.

UpToDate 2017: Dolutegravir: Drug information

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1/27/17	No	C. Sanders, MD	Annual Review
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1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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