VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

ZIAGEN® (Abacavir)

Effective Date: 7/24/12
Date Developed: 7/3/12 by Albert Reeves MD
Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20

ZIAGEN® is an Antiretroviral Agent, Reverse Transcriptase Inhibitor (Nucleoside)

Pre-Authorization Criteria:

VCHCP will authorize ZIAGEN®for FDA indicated treatment of treatment of HIV infections in combination with other antiretroviral agents.

ZIAGEN® is one of multiple products containing abacavir. Before starting ZIAGEN, review medical history for prior exposure to any abacavir-containing product in order to avoid reintroduction in a patient with a history of hypersensitivity to abacavir.

VCHCP requires that ZIAGEN be prescribed by an Infectious Disease specialist or HIV credentialed provider.

Dosing: Adult

HIV treatment: Oral: 300 mg twice daily or 600 mg once daily in combination with other antiretroviral agents

Dosing: Pediatric

HIV treatment: Oral:

Infants, Children, and Adolescents 3 months to <16 years: 8 mg/kg body weight twice daily (maximum: 300 mg twice daily) in combination with other antiretroviral agents. **Note:** May consider 16 to 20 mg/kg once daily dosing (maximum: 600 mg/day) in stable patients with undetectable viral load and stable CD4 count for more than 6 months (HHS [pediatric], 2014)

U.S. manufacturer labeling: Alternative dosing to be considered for pediatric patients ≥14 kg who are able to swallow tablets:

14 to 21 kg: 150 mg ($^1/_2$ tablet) twice daily

>21 kg to <30 kg: 150 mg ($^1/_2$ tablet) in the morning and 300 mg (1 tablet) in the evening

≥30 kg: 300 mg (1 tablet) twice daily

Adolescents ≥16 years: 300 mg twice daily or 600 mg once daily. **Note:** For patients who are HLA-B*5701 negative, abacavir is a component of a recommended regimen (with dolutegravir and lamivudine) for all treatment-naïve patients and a component of a recommended regimen (with efavirenz and lamivudine or with ritonavir boosted atazanavir and lamivudine) in treatment-naïve patients with pre-ART plasma HIV RNA <100,000 copies/mL (HHS [adult], 2014; HHS [pediatric], 2014).

Dosage Forms: U.S.

Solution, oral:

Ziagen®: 20 mg/mL (240 mL [DSC]) [strawberry-banana flavor]

Ziagen®: 20 mg/mL (240 mL) [contains propylene glycol; strawberry-banana flavor]

Tablet, oral:

Ziagen®: 300 mg [DSC]

Ziagen®: 300 mg [scored]

Warnings/Precautions

Contraindications:

ZIAGEN® (abacvir sulfate) tablets and oral solution are contraindicated in patients:

- With previously demonstrated hypersensitivity to abacavir, or any of the other components of the product (see WARNINGS AND PRECAUTIONS, and DOSAGE FORMS, COMPOSITION AND PACKAGING SECTIONS).
- With moderate or severe hepatic impairment since the pharmacokinetics have not been studied in this patient group.

Boxed warnings:

• Hypersensitivity reactions: Serious and sometimes fatal hypersensitivity reactions have been associated with abacavir therapy. Hypersensitivity to abacavir is a multiorgan clinical syndrome usually characterized by a sign or symptom in 2 or

more of the following groups:
-constitutional, including achiness, fatigue, or generalized malaise
-fever
-GI, including abdominal pain, diarrhea, nausea. or vomiting
-rash
-respiratory, including cough, dyspnea, or pharyngitis

- Lactic acidosis/hepatomegaly: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs alone or in combination, including abacavir and other antiretrovirals.

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