VENTURA COUNTY
HEALTH CARE PLAN

GENVOYA (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide)

Effective Date: 4/26/16

Date Developed: 4/14/16 by Dr. Robert Sterling

Date Approved by P&T Committee: 4/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20

Genvoya is a fixed-dose, four-drug combination tablet containing elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide (TAF), the latter being a newer form of tenofovir disoproxil fumarate (TDF). Genvoya is effective in reducing viral loads and comparable to other treatment regimens.

Elvitegravir is an HIV-1 integrase strand transfer inhibitor (INSTI), cobicistat, a CYP3A inhibitor, and emtricitabine and tenofovir alafenamide (TAF) are both HIV 1 nucleoside analog reverse transcriptase inhibitors (NRTIs).

Note: The advantages of Genvoya are that it is dosed once per day and that the new form of tenofovir provides lower levels of drug in the bloodstream, but higher levels within the cells where HIV-1 replicates, thus ostensibly reducing many side effects (particularly liver, kidney and bone toxicity). Thus, the focus in using this medication would be patients who have had intolerable side effects to the other regimens.

Pre-Authorization Criteria: adults and pediatric patients 12 years of age and older weighing at least 35 Kg (77 Lb) who have no antiretroviral treatment history (treatment naïve), or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to Genvoya's individual components. Patients should have a creatinine clearance of ≥ 30 mL/min.

Note: Not approved for treatment of Hepatitis B, for patients coinfected with HIV-1 and Hepatitis B, patients with Child-Pugh class C hepatic impairment. See Precautions.

Dosing: one tablet (150mg/150mg/200mg/10mg) daily with food

How Supplied: Combination tablet: 150mg elvitegravir /150mg elvitegravir /

200mg cobicistat /10mg tenofovir alafenamide

Precautions: Check hepatic and renal function before initiating therapy (not approved for patients co-infected with Hepatitis B, Child-Pugh Class C hepatic impairment or patients with Creatinine Clearance less than 30mL/min); decreased bone mineral density, fat redistribution and immune reconstitution syndrome

Boxed Warning: Genvoya can cause lactic acidosis and liver failure (severe hepatomegaly and steatosis), both of which can be fatal. Genvoya is not approved to treat chronic Hepatitis B infection.

Drug Interactions: medications metabolized by CYP3A and CYP2D6 enzymes

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