VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Catherine Sanders, MD

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Stribild is combination of- Integrase strand transfer inhibitor, CYP3A enzyme inhibitor plus nucleoside and nucleotide reverse transcriptase inhibitor. Elvitegravir inhibits the catalytic activity of integrase, thus preventing integration of the proviral gene into human DNA. Cobicistat inhibits enzymes of the CYP3A subfamily and enhances systemic exposure to elvitegravir. Emtricitabine is a cytosine analogue and tenofovir disoproxil fumarate (TDF) is an analog of adenosine 5'-monophosphate. Emtricitabine and tenofovir interfere with HIV viral RNA dependent DNA polymerase activities resulting in inhibition of viral replication.

Pre-Authorization Criteria:

1) Treatment of HIV-1 infection in adults and pediatric patients ≥12 years weighing ≥35 kg who are antiretroviral treatment-naïve
2) As a replacement for the current antiretroviral regimen in patients who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for ≥6 months with no history of treatment failure and no known substitutions associated with resistance to elvitegravir, cobicistat, emtricitabine, or tenofovir disoproxil fumarate.

NOTE: Stribild is not recommended for use concomitantly with other antiretroviral drugs due to the potential for drug interactions and lack of dosing recommendations.

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

NOTE: Use in patients with creatinine clearance less than 70 mL/minute is not recommended and is not to be continued in patients with a creatinine clearance of <50 mL/minute during therapy.
Not for use in treatment-experienced patients
Not for use in patients with ESRD requiring dialysis.

Dosing: Adult:
HIV-1: Oral: One tablet once daily with food.
Dosage Forms: U.S.:
Tablet, oral:
Stribild™: Elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg, and tenofovir disoproxil fumarate 300 mg

Contraindications:
Concurrent use of alfuzosin, cisapride, ergot derivatives (eg, dihydroergotamine, ergotamine, methylergonovine); lovastatin, midazolam (oral), pimozide, rifampin, sildenafil (when used for pulmonary arterial hypertension), simvastatin, St John's wort, triazolam

Adverse Reactions:
>10%: nausea, diarrhea, proteinuria
Other Severe Less Common Reactions: lactic acidosis, hepatomegaly, hepatotoxicity, HBV exacerbation, post-treatment, nephrotoxicity, rhabdomyolysis, myopathy, osteomalacia, fractures, pancreatitis, neutropenia, immune reconstitution syndrome, autoimmune disorders, hypersensitivity reaction, fat redistribution.

U.S.BOXED WARNINGS:
Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, associated with nucleoside analogue use alone or in combination; suspend treatment if clinical or laboratory findings suggest lactic acidosis or hepatotoxicity.

Severe, acute exacerbations of hepatitis B have been reported in patients who are coinfected with HBV and HIV-1 and have discontinued emtricitabine or tenofovir disoproxil fumarate. Hepatic function should be monitored closely, with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue this fixed-dose combination. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

References:

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2. DHHS 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," February 12, 2013;1-267. Available at http://www.aidsinfo.nih.gov
3. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents, Statement Update: "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, Department of Health and Human Services," September 18, 2012b. Available at http://www.aidsinfo.nih.gov
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6. Sax PE, DeJesus E, Mills A, et al, "Co-Formulated Elvitegravir, Cobicistat, Emtricitabine, and Tenofovir Versus Co-Formulated Efavirenz, Emtricitabine, and Tenofovir for Initial Treatment of HIV-1 Infection: A Randomised, Double-Blind, Phase 3 Trial, Analysis of Results After 48 Weeks," Lancet, 2012, 379(9835):2439-48
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9. Purdy JB, Gafni RI, Reynolds JC, Zeichner S, Hazra R. Decreased bone mineral density with off-label use of tenofovir in children and adolescents infected with human immunodeficiency virus. J Pediatr. 2008;152(4):582-584.
10. Fulco PP, Ayala-Sims VA. Sustained virological response after taking crushed elvitegravir-cobicistat-emtricitabine-tenofovir tablets. Am J Health Syst Pharm. 2014;71(10):784, 786. doi: 10.2146/ajhp130737.
11. Jongbloed-de Hoon M, Colbers A, Velthoven-Graafland K, et al. Brief report: pharmacokinetics of crushed elvitegravir combination tablet given with or without enteral nutrition. J Acquir Immune Defic Syndr. 2017;74(5):571-574.

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1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Modified preauthorization criteria with "Treatment of HIV-1 infection in adults and pediatric patients ≥12 years weighing ≥35 kg who are antiretroviral treatment-naïve" Updated US Boxed warnings and references