VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

EMTRIVA (Emtricitabine)

Effective Date: 7/28/05

Date Developed: 7/14/05 by C. Wilhelmy MD

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Emtriva is an Antiretroviral Agent, Reverse Transcriptase Inhibitor (Nucleoside). It is a cytosine analogue which is phosphorylated intracellularly to emtricitabine 5'-triphosphate which interferes with HIV viral RNA dependent DNA polymerase resulting in inhibition of viral replication.

Pre-Authorization Criteria:

treatment of HIV infection in combination with at least two other antiretroviral agents.

Note: VCHCP requires that it be prescribed by an Immunology Clinic physician or physician boarded in Infectious Disease.

DOSING: ADULTS — HIV infection: Oral: 200 mg once daily DOSING:

ELDERLY — Refer to adult dosing.

DOSING: RENAL IMPAIRMENT
Clcr 30-49 mL/minute: 200 mg every 48 hours; Clcr 15-29 mL/minute: 200 mg every 72 hours; Clcr<15 mL/minute (including hemodialysis patients): 200 mg every 96 hours

DOSING: HEPATIC IMPAIRMENT — No adjustment required.

ADMINISTRATION — May be administered with or without food.

CONTRAINDICATIONS — Hypersensitivity to emtricitabine or any component of the formulation

WARNINGS / PRECAUTIONS — Lactic acidosis, severe hepatomegaly, and hepatic failure have occurred rarely with emtricitabine (similar to other nucleoside analogues). Some cases have been fatal; stop treatment if lactic acidosis or hepatotoxicity occur. Prior liver disease, obesity, extended duration of therapy, and female gender may represent risk factors for severe hepatic reactions. Testing for hepatitis B is recommended prior to the initiation of therapy; hepatitis B may be exacerbated following discontinuation of emtricitabine. Use caution in patients with renal impairment (dosage adjustment required).

MONITORING PARAMETERS — Viral load, CD4, liver function tests; hepatitis B testing is recommended prior to initiation of therapy

DRUG INTERACTIONS — Note: Limited drug interaction data available. No evidence of a clinically-significant interaction when administered with tenofovir, indinavir, famciclovir, or stavudine.

Ribavirin: Concomitant use of ribavirin and nucleoside analogues may increase the risk of developing lactic acidosis.

ETHANOL / NUTRITION / HERB INTERACTIONS — Food: Food decreases peak plasma concentrations, but does not alter the extent of absorption or overall systemic exposure.

PREGNANCY RISK FACTOR — B

PREGNANCY IMPLICATIONS — Cases of fatal and nonfatal lactic acidosis, with or without pancreatitis, have been reported in pregnant women receiving reverse transcriptase inhibitors. It is not known if pregnancy itself potentiates this known side effect; however, pregnant women may be at increased risk of lactic acidosis and liver damage. Hepatic enzymes and electrolytes should be monitored frequently during the 3rd trimester of pregnancy. There are no studies of emtricitabine during pregnancy. The Perinatal HIV Guidelines Working Group considers emtricitabine to be an alternative NRTI in dual nucleoside combination regimens. Health professionals are encouraged to contact the antiretroviral pregnancy registry to monitor outcomes of pregnant women exposed to antiretroviral medications (1-800-258-4263 or www.APRegistry.com).

LACTATION — Excretion in breast milk unknown/not recommended

BREAST-FEEDING CONSIDERATIONS — HIV-infected women are discouraged from breast-feeding to decrease the potential transmission of HIV.

PATIENT EDUCATION — It is not a cure for HIV and does not reduce transmission of HIV. May cause headache, dizziness (use caution when driving or engaging in potentially hazardous tasks until response to drug is known); nausea, vomiting, (small, frequent meals, frequent mouth care, chewing gum, or sucking lozenges may help). May cause changes in skin pigmentation, especially on soles and palms. Report muscle weakness or pain; tingling, numbness, or pain in toes or fingers; weakness of extremities; chest pain, palpitations, or rapid heartbeat; swelling of extremities; weight gain or loss >5 lb/week; signs of infection (eg, fever, chills, sore throat,burning urination, fatigue); unusual bleeding (eg, tarry stools, easy bruising, or blood in stool, urine, or mouth); skin rash or irritation.

REFERENCES

1. Cahn, P, Raffi, F, Saag, M, et al. Virologic Efficacy and Patterns of Resistance Mutations in ART-Naive Patients Receiving Combination Therapy with Once-Daily (QD) Emtricitabine Compared to Twice-Daily (BID) Stavudine in a Randomized, Double-blind, Multi-center Clinical Trial (Poster 606).

Presented at the 10th Conference on Retroviruses and Opportunistic Infections, Boston, MA, February 10-14, 2003. Available at: http://www.retroconference.org/Archive/Posters/Retro10/606.pdf. Accessed July 9, 2003.
2. Gish, RG, Leung, NW, Wright, TL, et al. Dose Range Study of Pharmacokinetics, Safety, and Preliminary Antiviral Activity of Emtricitabine in Adults With Hepatitis B Virus Infection. Antimicrob Agents Chemother 2002; 46:1734.
3. Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States. June 23 2004. Available at: http://www.aidsinfo.nih.gov. Accessed July 1; 2004.
4. Saag, M, Cahn, P, Raffi, F, et al. A Randomized, Double-Blind, Multicenter Comparison of Emtricitabine QD to Stavudine BID (Oral Presentation LB-1). Presented at the 42nd International Conference on Antimicrobial Agents and Chemotherapy, San Diego, CA, September 27-20, 2002.
5. Sanne, I, van der Horst, C, Shaw, A, et al. Two Randomized, Controlled, Equivalence Trials of Emtricitabine (FTC) to Lamivudine (3TC). Presented at the 14th International AIDS Conference, Barcelona, Spain, July 7-12, 2002. Available at: http://www.aids2002.com/Program/ViewAbstract.asp?id=/T-CMS_Content/Abstract/200 Accessed July 9, 2003.

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