VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

EPIVIR/EPIVIR-HBV (Lamivudine)

Effective Date: 1/28/14

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

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Lamivudine is a cytosine analog. Its principle mode of action is inhibition of HIV reverse transcription via viral DNA chain termination and thus inhibits RNA- and DNA-dependent DNA polymerase activities of reverse transcriptase. In hepatitis B, lamivudine is incorporated into the viral DNA by hepatitis B virus polymerase, resulting in DNA chain termination.

Pre-Authorization Criteria: treatment of chronic hepatitis B associated with evidence of hepatitis B viral replication and active liver inflammation; HIV infection in combination with other antiretroviral agents
Note: Use only if other anti-HBV agents with more favorable resistance patterns have failed or cannot be used; has not been evaluated in patients with HBV-HIV-1 coinfection

NOTE: The formulation and dosage of Epivir-HBV® are not appropriate for patients infected with both HBV and HIV.

Off-Label: nonoccupational postexposure prophylaxis for HIV exposure (as a component of a multidrug regimen). Prevention of perinatal HIV transmission

Note: Use with caution; heightened risk of causing significant patient harm when used in error.

Dosing: Adult:

HIV: Oral (use with at least two other antiretroviral agents): 150 mg twice daily or 300 mg once daily; <50 kg: 4 mg/kg twice daily (maximum: 150 mg twice daily)

Postexposure prophylaxis for HIV exposure (unlabeled use [CDC, 2005]): Oral: 150 mg/dose twice daily or 300 mg/dose once daily (in combination with zidovudine, tenofovir, stavudine, or

didanosine, with or without a protease inhibitor depending on risk). Initiate therapy within 72 hours of exposure and continue for 28 days

Treatment of hepatitis B: Oral: 100 mg/day

Treatment duration (AASLD practice guidelines): Treatment duration for nucleos(t)ide analog–based therapy (eg, lamivudine) is variable and influenced by HBeAg status, duration of HBV suppression, and presence of cirrhosis/decompensation. Refer to current Guidelines.

Adverse Reactions:
>10%: Headache, fatigue, insomnia, nausea, diarrhea, pancreatitis, abdominal pain, vomiting, neutropenia, transaminases increased, myalgia, neuropathy, musculoskeletal pain, nasal signs and symptoms, cough, sore throat.
Other Severe Less Common Reactions: fat redistribution, immune reconstitution syndrome, lactic acidosis/hepatomegaly, HBV exacerbation, post treatment, peripheral neuropathy, rhabdomyolysis, anemia, severe, anaphylaxis, autoimmune disorders.

U.S. BOXED WARNING:
Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, associated with nucleoside analogue used alone or in combination; suspend treatment if clinical or laboratory findings suggest lactic acidosis or hepatotoxicity.
Lamivudine dosage forms contain higher dose used to treat HIV compared to lamivudine-HBV dosage forms used to treat chronic HBV; ensure patients receive correct dosage form for indicated use.
Severe acute HBV exacerbations in HBV/HIV co-infected patients upon lamivudine discontinuation; monitor hepatic function closely for at least several months in HBV/HIV co-infected patients who discontinue abacavir/lamivudine; initiate anti-HBV treatment if needed.
Lamivudine-HBV is not approved for the treatment of HIV-1 infection because the lamivudine dosage in lamivudine-HBV is subtherapeutic and monotherapy is inappropriate for the treatment of HIV-1 infection. HIV-1 resistance may emerge in chronic hepatitis B-infected patients with unrecognized or untreated HIV-1 infection. HIV counseling and testing should be offered to all patients before beginning treatment with lamivudine-HBV and periodically during treatment

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21. Epivir HBV (lamivudine) [prescribing information]. Research Triangle Park, NC; GlaxoSmithKline; December 2021

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1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Replaced Epivir background to Lamivudine. Added "**Note:** Use only if other anti-HBV agents with more favorable resistance patterns have failed or cannot be used; has not been evaluated in patients with HBV-HIV-1 coinfection. **NOTE**: The formulation and dosage of Epivir-HBV® are not appropriate for patients infected with both HBV and HIV. "Updated dosing & US Boxed warning sections