

## Prior Authorization DRUG Guidelines

### EPZICOM (abacavir and lamivudine)

Effective Date: 1/28/14

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

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20

Epzicom is an Antiretroviral Agent, Reverse Transcriptase Inhibitor (Nucleoside) used in the treatment of HIV-1 infection. Abacavir is a guanosine analogue which is phosphorylated to carbavir triphosphate which interferes with HIV viral RNA-dependent DNA polymerase resulting in inhibition of viral replication. Lamivudine is a cytosine analog. After lamivudine is triphosphorylated, the principle mode of action is inhibition of HIV reverse transcription via viral DNA chain termination; inhibits RNA-dependent DNA polymerase activities of reverse transcriptase.

**Pre-Authorization Criteria:** Treatment of HIV infections in combination with other antiretroviral agents

**Note:** Patients must have a creatinine clearance >50mL/minute and have no hepatic impairment.

**Note:** Patients who carry the HLA-B\*5701 allele are at high risk for experiencing a hypersensitivity reaction to abacavir. Prior to initiating therapy with abacavir, screening for the HLA-B\*5701 allele is recommended

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

**Note:**

An FDA-approved patient **Medication Guide**(available with the product information and at <http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088592.pdf>), must be dispensed with this medication.

A **Warning Card** (summarizing symptoms of hypersensitivity), which is available with the product information, must also be dispensed with this medication for each new outpatient prescription and refill.

**Dosing: Adult:**

HIV: Oral: One tablet (abacavir 600 mg and lamivudine 300 mg) once daily

**Dosing: Pediatric:**

Pediatric dosing is currently unavailable or not applicable for this drug.

**Dosing: Renal Impairment:**

Cl<sub>cr</sub> <50 mL/minute: Use not recommended

**Dosing: Hepatic Impairment :**

Use contraindicated.

**Dosage Forms: U.S.:**

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Tablet:

Epzicom®: Abacavir 600 mg and lamivudine 300 mg

Generic Equivalent Available: U.S.-No

**Administration:**

May be administered with or without food.

**Exclusions:**

Do not use in patients with creatinine clearance <50 mL/minute. Dose adjustment not possible with fixed-dose tablets.

Contraindicated in patients with hepatic impairment. Dosage adjustment not possible with fixed-dose tablets.

Do not use in patients testing positive for the HLA-B\*5701 allele.

Do not rechallenge patient who have experienced hypersensitivity to abacavir regardless of HLA-B\*5701 status.

Concomitant use of emtricitabine-containing products should be avoided due to possible development of cross-resistance.

**Adverse Reactions:**

See individual agents.

Severe Reactions: fat redistribution, hypersensitivity reactions, immune reconstitution syndrome, lactic acidosis/hepatomegaly, Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, MI, pancreatitis, HBV exacerbation, post-treatment, peripheral neuropathy, anemia, severe, rhabdomyolysis, autoimmune disorders.

**U.S. BOXED WARNING:**

Severe or fatal hypersensitivity reaction/multi-organ clinical syndrome with signs and symptoms from greater than 2 of the following groups: 1)fever, 2)rash, 3)GI (nausea, vomiting, diarrhea, or abdominal pain), 4)constitutional (malaise, fatigue, or achiness), and 5)respiratory (dyspnea, cough, or pharyngitis); carriers of HLA-B\*5701 allele are at higher risk of hypersensitivity reactions; HLA-B\*5701 allele screening recommended prior to treatment or reinitiation of treatment in patients of unknown HLA-B\*5701 status who have previously tolerated abacavir; permanently discontinue if hypersensitivity reaction suspected or cannot be ruled out, regardless of HLA-B\*5701 status; NEVER restart after hypersensitivity reaction as more severe symptoms may occur within hours, including life-threatening hypotension or death; reaction may occur within hours of restarting even in patients without hypersensitivity reaction history. 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 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.

**References:**

1. 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>
2. Lucas A, Nolan D, and Mallal S, "HLA-B\*5701 Screening for Susceptibility to Abacavir Hypersensitivity," *J Antimicrob Chemother*, 2007, 59(4):591-3. [PubMed 17317695]
3. Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children, "Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection," August 16, 2010. Available at <http://www.aidsinfo.nih.gov>
4. [www.uptodate.com](http://www.uptodate.com): Abacavir and lamivudine Drug Information.
5. [www.epocrates.com](http://www.epocrates.com): Epzicom Drug Information.

**REVISION HISTORY:**

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD  
 Date Approved by P&T Committee: 1/27/15  
 Date Reviewed/Updated: 3/10/15 by C. Sanders, MD; R. Sterling, MD  
 Date Approved by P&T Committee: 1/26/16  
 Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD  
 Date Approved by P&T Committee: 1/24/17  
 Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD  
 Date Approved by P&T Committee: 1/23/18  
 Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD  
 Date Approved by P&T Committee: 1/22/19  
 Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD  
 Date Approved by P&T Committee: 2/18/20

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD;	Annual review

		Robert Sterling, MD	
2/18/20		Howard Taekman, MD; Robert Sterling, MD	Annual review