

Prior Authorization DRUG Guidelines

Videx (didanosine)

Effective Date 01/24/2017

Developed 12/07/2016 by R. Sterling, MD

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Didanosine, a purine nucleoside (adenosine) analog which inhibits HIV replication in both T cells and monocytes. Its metabolites act as substrate and inhibitor of HIV reverse transcriptase thereby blocking viral DNA synthesis and as a result suppressing HIV replication.

Pre-authorization Criteria: treatment of HIV-1 infection in combination with other antiretroviral agents

Note:

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

Dosing: 25 kg to <60 kg: 250 mg once daily

≥60 kg: 400 mg once daily

How Supplied: capsule: 125 mg, 200 mg, 250 mg, 400 mg

Adverse Reactions/Precautions: U.S Boxed Warning: 1) Lactic acidosis and severe hepatomegaly with steatosis have been reported, including fatal cases, with nucleoside analogues, alone or in combination, including didanosine and other antiretrovirals; 2) Pancreatitis (fatal and nonfatal) has been reported alone or in combination regimens in both treatment-naïve and treatment-experienced patients, regardless of degree of immunosuppression. Suspend use in patients with suspected pancreatitis and discontinue in patients with confirmed pancreatitis; central fat redistribution; immune reconstitution syndrome; peripheral neuropathy; optic neuritis; administer on an empty stomach (absorption is significantly decreased with food)

Drug Interactions: numerous; see product literature

REFERENCES:

Faulds D and Brogden RN, "Didanosine: A Review of Its Antiviral Activity, Pharmacokinetic Properties and Therapeutic Potential in Human Immunodeficiency Virus Infection," *Drugs*, 1992, 44(1):94-116.

HHS Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents.
<http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Updated April 8, 2015. Accessed July 8, 2015.

Morse GD, Shelton MJ, and O'Donnell AM, "Comparative Pharmacokinetics of Antiviral Nucleoside Analogues," *Clin Pharmacokinet*, 1993, 24(2):101-23.

Perry CM and Balfour JA, "Didanosine. An Update on Its Antiviral Activity, Pharmacokinetic Properties, and Therapeutic Efficacy in the Management of HIV Disease," *Drugs*, 1996, 52(6):928-62

Rathbun RC and Martin ES 3d, "Didanosine Therapy in Patients Intolerant of or Failing Zidovudine Therapy," *Ann Pharmacother*, 1992, 26(11):1347-51

Videx EC (didanosine) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; December 2012.

Videx EC (didanosine) [product monograph]. Montreal, Canada: Bristol-Myers Squibb Canada; April 2016.

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