

Prior Authorization DRUG Guidelines

VIDEX/VIDEX EC (Didanosine)

Effective Date: 1/28/14

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

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Videx/Videx EC is an Antiretroviral, Reverse Transcriptase Inhibitor (Nucleoside) used in the treatment of HIV-1 infections. Didanosine, a purine nucleoside (adenosine) analog and the deamination product of dideoxyadenosine (ddA), inhibits HIV replication *in vitro* in both T cells and monocytes. Didanosine is converted within the cell to the mono-, di-, and triphosphates of ddA. These ddA triphosphates act as substrate and inhibitor of HIV reverse transcriptase substrate and inhibitor of HIV reverse transcriptase thereby blocking viral DNA synthesis and suppressing HIV replication.

Pre-Authorization Criteria:

Videx is used for treatment of HIV-1 infections, always to be used in combination with at least two other antiretroviral agents.

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

An FDA-approved patient medication guide, which is available with the product information and as follows, must be dispensed with this medication:

Videx®: <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM199211.pdf>

Videx® EC: <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM199212.pdf>

Dosing: Adult:

Treatment of HIV infection: Oral:

Dosing based on patient weight:

Pediatric powder for oral solution (Videx®):

<60 kg: 125 mg twice daily (preferred) or 250 mg once daily

≥60 kg: 200 mg twice daily (preferred) or 400 mg once daily

Delayed release capsule (Videx® EC):

25 kg to <60 kg: 250 mg once daily

≥60 kg: 400 mg once daily

When taken with tenofovir:

<60 kg and Cl_{cr} ≥60 mL/minute: 200 mg once daily

≥60 kg and Cl_{cr} ≥60 mL/minute: 250 mg once daily

Note: Combined use of tenofovir with didanosine is no longer recommended (DHHS, 2013).

Dosing: Pediatric:

Treatment of HIV infection: Oral:

Pediatric powder for oral solution (Videx®): Note: Once-daily dosing of the oral solution is not FDA approved in children.

Infants: 2 weeks to 8 months: 100 mg/m² twice daily is recommended by the manufacturer; 50 mg/m² may be considered in infants 2 weeks to <3 months (DHHS [pediatric], 2011)

Infants and Children >8 months: 120 mg/m² twice daily, not to exceed adult dose, is recommended by the manufacturer. Note: DHHS guidelines suggest a range of 90-150 mg/m² twice daily

Adolescents: Dosing based on patient weight: Refer to adult dosing.

Children 3-21 years (unlabeled dose): Treatment-naive: 240 mg/m²/dose once daily (maximum: 400 mg/dose) (DHHS [pediatric], 2011)

Delayed release capsule (Videx® EC):

Children ≥6 years:

20 kg to <25 kg: 200 mg once daily

25 kg to <60 kg: 250 mg once daily

≥60 kg: 400 mg once daily

Children 3-21 years (unlabeled dose): Treatment-naive: 240 mg/m²/dose once daily (maximum: 400 mg/dose) (DHHS [pediatric], 2011)

Dosing: Geriatric:

Refer to adult dosing. Elderly patients have a higher frequency of pancreatitis (10% versus 5% in younger patients); monitor renal function and dose accordingly.

Dosing: Renal Impairment :

Children: No specific guidelines available; consider dosage reduction using adjustments for adults.

Adults: Dosing based on patient weight, creatinine clearance, and dosage form: See table.

Recommended Dose (mg) of Didanosine by Body Weight – Adults				
Creatinine Clearance (mL/min)	≥60 kg		<60 kg	
	Powder for Oral Solution	Delayed Release Capsule	Powder for Oral Solution	Delayed Release Capsule
Note: Per manufacturer, not suitable for use in patients <60 kg with Cl _{cr} <10 mL/minute; use alternate formulation.				
≥60	400 mg daily or 200 mg twice daily	400 mg daily	250 mg daily or 125 mg twice daily	250 mg daily
30-59	200 mg daily or 100	200 mg daily	150 mg daily or 75 mg	125 mg daily

Recommended Dose (mg) of Didanosine by Body Weight – Adults

Creatinine Clearance (mL/min)	≥60 kg		<60 kg	
	Powder for Oral Solution	Delayed Release Capsule	Powder for Oral Solution	Delayed Release Capsule
	mg twice daily		twice daily	
10-29	150 mg daily	125 mg daily	100 mg daily	125 mg daily
<10	100 mg daily	125 mg daily	75 mg daily	See Note.

Patients requiring hemodialysis or CAPD: Dose per Cl_{cr} <10 mL/minute. Didanosine is not removed via CAPD and minimal amount of dose ($\leq 7\%$) is removed by hemodialysis; no supplemental dosing necessary.

Dosing: Hepatic Impairment:

No dosage adjustment needed.

Dosage Forms: U.S.:

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

Capsule Delayed Release, Oral:

Videx EC: 125 mg, 200 mg, 250 mg, 400 mg

Generic: 125 mg, 200 mg, 250 mg, 400 mg

Solution Reconstituted, Oral:

Videx: 2 g (100 mL); 4 g (200 mL)

Generic Equivalent Available: U.S.-May be product dependent

Administration:

Pediatric powder for oral solution: Administer on an empty stomach at least 30 minutes before or 2 hours after eating. Shake well prior to use.

Videx® EC: Administer on an empty stomach at least 1 hour before or 2 hours after eating; swallow capsule whole.

Contraindications:

Concurrent administration with allopurinol or ribavirin

Adverse Reactions:

Note: risk of toxicity may increase when combined with other agents.

>10%: Diarrhea, amylase increased, abdominal pain, peripheral neuropathy

Other Serious Less Common Reactions: pancreatitis, hepatotoxicity, non-cirrhotic portal hypertension, lactic acidosis, optic neuritis, immune reconstitution syndrome, neutropenia, thrombocytopenia, diabetes mellitus, rhabdomyolysis, autoimmune disorders, fat redistribution.

U.S. BOXED WARNING:

Fatal and nonfatal pancreatitis reported with didanosine monotherapy or combination regimens in both treatment-naïve and treatment-experienced patients regardless of degree of immunosuppression; suspend treatment in suspected pancreatitis and discontinue if confirmed pancreatitis. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, associated with nucleoside analogue use alone or in combination; fatal lactic acidosis reported in pregnant patients on didanosine/stuvudine combination, use only if benefits outweigh risks.

References:

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12. 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. [PubMed 8957161]
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15. www.uptodate.com: Didanosine: Drug Information

16. www.epocrates.com: Videx Drug Information

Revision History:

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