VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

ZERIT (Stavudine)

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

Zerit is an Antiretroviral Agent, Reverse Transcriptase Inhibitor (Nucleoside) used in the treatment of HIV-1 infections. It is a thymidine analog which interferes with HIV viral DNA dependent DNA polymerase resulting in inhibition of viral replication; nucleoside reverse transcriptase inhibitor.

Pre-Authorization Criteria:
Zerit is to be used for treatment of HIV-1 infections in combination with other antiretroviral agents.

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

Medication Guide:
An FDA-approved patient medication guide, which is available with the product information and at http://www.fda.gov/downloads/Drugs/DrugSafety/UCM238427.pdf, must be dispensed with this medication.

Dosing: Adult:
HIV infection (in combination with other antiretrovirals): Oral:
<60 kg: 30 mg every 12 hours
≥60 kg: 40 mg every 12 hours
Note: The World Health Organization recommends 30 mg every 12 hours in all adult and adolescent patients regardless of body weight (DHHS, 2012).

Dosing: Pediatric:
HIV infection: Oral:
Newborns (Birth to 13 days): 0.5 mg/kg every 12 hours
Children:
≥14 days and <30 kg: 1 mg/kg every 12 hours
≥30 kg: Refer to adult dosing.

Administration:
May be administered without regard to meals. Oral solution should be shaken vigorously prior to use.

Dosing: Geriatric:
Older patients should be closely monitored for signs and symptoms of peripheral neuropathy. Dosage should be carefully adjusted to renal function.

Dosing: Renal Impairment:
Children: Specific recommendations not available. Reduction in dose or increase in dosing interval should be considered.
Adults:
Cl_{cr} >50 mL/minute:
<60 kg: 30 mg every 12 hours
≥60 kg: 40 mg every 12 hours
Cl_{cr} 26-50 mL/minute:
<60 kg: 15 mg every 12 hours
≥60 kg: 20 mg every 12 hours
Cl_{cr} 10-25 mL/minute, hemodialysis (administer dose after hemodialysis on day of dialysis):
<60 kg: 15 mg every 24 hours
≥60 kg: 20 mg every 24 hours

Dosing: Hepatic Impairment:
No dosage adjustment provided in manufacturer's labeling. Use with caution.

Dosage Forms: U.S.:
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.
Capsule, Oral:
Zerit: 15 mg, 20 mg, 30 mg, 40 mg
Generic: 15 mg, 20 mg, 30 mg, 40 mg
Solution Reconstituted, Oral:
Zerit: 1 mg/mL (200 mL) [dye free; fruit flavor]
Generic: 1 mg/mL (200 mL)

Generic Equivalent Available: U.S.-Yes

Exclusions:
Zerit is not to be used as monotherapy.
Zerit is not to be used in combination with Zidovudine.

Adverse Reactions:
>10%: Headache, rash, nausea, vomiting, diarrhea, hyperbilirubinemia, AST increased, ALT increased, GGT increased, peripheral neuropathy, amylase increased, lipase increased.
Other Severe Less Common Reactions: Immune reconstitution syndrome, fat redistribution, lactic acidosis/hepatomegaly, severe motor weakness (resembling Guillain-Barré syndrome), pancreatitis, hyperlactatemia, hepatotoxicity, leukopenia, thrombocytopenia, anemia, neutropenia, diabetes mellitus, hyperglycemia, autoimmune disorders.

U.S.BOXED WARNING:
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/stavudine combination, use only if benefits outweigh risks.

Fatal and nonfatal pancreatitis reported with stavudine and didanosine combination regimen with or without hydroxyurea in both treatment-naïve and treatment-experienced patients regardless of the degree of immunosuppression.

References:

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2. 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
3. DHHS Panel on Opportunistic Infections (OI) in HIV-Infected Adults and Adolescents, "Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents: Recommendations from the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA)," May 7, 2013. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf
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5. Hilts AE and Fish DN, "Dosage Adjustment of Antiretroviral Agents in Patients With Organ Dysfunction," *Am J Health Syst Pharm*, 1998, 55:2528-33. [PubMed 9853641]
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8. Sandstrom E and Oberg B, "Antiviral Therapy in Human Immunodeficiency Virus Infections. Current Status," *Drugs*, 1993, 45(4):488-508. [PubMed 7684670]
9. 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
10. www.uptodate.com: Stavudine Drug Information
11. www.epocrates.com: Stavudine Drug Information

Revision History:

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