VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

VIRACEPT (Nelfinavir)

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

Viracept is an Antiretroviral Agent, Protease Inhibitor used in the treatment of HIV-1 infections. Viracept binds to the site of HIV-1 protease activity and inhibits cleavage of viral Gag-Pol polyprotein precursors into individual functional proteins required for infectious HIV. This results in the formation of immature, noninfectious viral particles.

Pre-Authorization Criteria:
Viracept is used for the treatment of patients with HIV-1 infection in combination with other antiretroviral therapy.

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

Dosing: Adult:
HIV infection: Oral: 750 mg 3 times/day or 1250 mg twice daily with meals in combination with other antiretroviral therapies. Note: The DHHS Perinatal HIV Guidelines do not recommend the 3 times/day dosing in pregnant women (DHHS [perinatal], 2012).

Dosing: Pediatric:
HIV infection: Oral: Children 2-13 years: 45-55 mg/kg twice daily or 25-35 mg/kg 3 times/day (maximum: 2500 mg/day). If tablets are unable to be taken, use oral powder in small amount of water, milk (cow's or soy), formula, or dietary supplements; do not use acidic food/juice or store for >6 hours.

Administration:
Oral powder: Administer reconstituted powder with a meal. Be sure entire contents is consumed to receive full dose.
Tablets: Administer with a meal. If unable to swallow tablets, may dissolve tablets in a small amount of water; mix cloudy liquid well and consume immediately. Rinse glass with water to ensure receiving full dose. Tablets may also be crushed and mixed with pudding.

Dosing: Geriatric:
Refer to adult dosing.

Dosing: Renal Impairment:
No dosage adjustment provided in manufacturer's labeling (has not been studied). However, since <2% excreted in urine a dosage reduction would not be expected

Dosing: Hepatic Impairment:
No dosage adjustment necessary in mild impairment (Child-Pugh class A); not recommended in patients with moderate-to-severe impairment (Child-Pugh class B or C)

Dosage Forms: U.S.:
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.
Tablet, Oral:
Viracept: 250 mg, 625 mg
Generic Equivalent Available: U.S.-No

Adverse Reactions:
>10%: diarrhea
Other Serious Less Common Reactions: immune reconstitution syndrome, fat redistribution, hyperglycemia, diabetes mellitus, hypercholesterolemia, hypertriglyceridemia, pancreatitis, hepatotoxicity, leukopenia, thrombocytopenia, anemia, hypersensitivity reaction, autoimmune disorders

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. Lok AS and McMahon BJ, "Chronic Hepatitis B," *Hepatology*, 2007, 45(2):507- 39. [PubMed 17256718]
3. Microbicide Trials Network (MTN), "MTN Statement on Decision to Discontinue Use of Oral Tenofovir Tablets in VOICE, a Major HIV Prevention Study in Women," *Microbicide Trials Network*, 2011. Available at http://www.mtnstopshiv.org/node/3619.
4. www.uptodate.com: Nelfinavir: Drug Information
5. www.epocrates.com: Viracept Drug Information

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