VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

CRIXIVAN (Indinavir)

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

Crixivan is an Antiretroviral Agent, Protease Inhibitor used in the treatment of HIV-1 infection. Crixivan 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: treatment of HIV infection
Note: should always be used as part of a multidrug regimen (at least three antiretroviral agents)

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

Note: Crixivan use in pediatric patients is investigational and therefore an excluded benefit.

Dosing: Adult:
HIV infection: Oral:
Unboosted regimen: 800 mg every 8 hours
Ritonavir-boosted regimen: Ritonavir 100-200 mg twice daily plus indinavir 800 mg twice daily

Dosage adjustments for indinavir when administered in combination therapy:
Delavirdine, itraconazole, or ketoconazole: Reduce indinavir dose to 600 mg every 8 hours
Efavirenz: Increase indinavir dose to 1000 mg every 8 hours
Lopinavir and ritonavir (Kaletra™): Indinavir 600 mg twice daily
Nelfinavir: Increase indinavir dose to 1200 mg twice daily
Nevirapine: Increase indinavir dose to 1000 mg every 8 hours
Rifabutin: Reduce rifabutin to $^1/_2$ the standard dose plus increase indinavir to 1000 mg every 8 hours

Dosing: Pediatric:
HIV: Children 4-15 years (investigational): 500 mg/m^2 every 8 hours

Dosing: Geriatric:
Refer to adult dosing.

Dosing: Renal Impairment:
No dosage adjustment provided in manufacturer's labeling (has not been studied).

Dosing: Hepatic Impairment:

Mild-moderate impairment due to cirrhosis, monotherapy: 600 mg every 8 hours
Severe impairment: No dosage adjustment provided in the manufacturer's labeling (has not been studied).

Dosage Forms: U.S.:
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.
Capsule, Oral:
Crixivan: 200 mg, 400 mg

Generic Equivalent Available: U.S.-No

Administration:
Drink at least 48 oz of water daily. Administer with water, 1 hour before or 2 hours after a meal. May also be administered with other liquids (eg, skim milk, juice, coffee, tea) or a light meal (eg, toast, corn flakes). Administer around-the-clock to avoid significant fluctuation in serum levels. May be taken with food when administered in combination with ritonavir.

Contraindications:
Hypersensitivity to indinavir or any component of the formulation; concurrent use of alfuzosin, alprazolam, amiodarone, cisapride, ergot alkaloids, lovastatin, midazolam (oral), pimozide, simvastatin, St. John's wort, or triazolam; sildenafil (when used for pulmonary artery hypertension [eg, Revatio®]).

Exclusions:
Pediatric use is investigational and therefore an excluded benefit (see EOC).

Adverse Reactions:
>10%-Abdominal pain, nausea, hyperbilirubinemia, nephrolithiasis/urolithiasis, including flank pain with/without hematuria.
Other Severe Less Common Reactions: interstitial nephritis, hyperglycemia, diabetes mellitus, hypercholesterolemia, hypertriglyceridemia, pancreatitis, hepatotoxicity, Stevens-Johnson syndrome, erythema multiforme, hemolytic anemia, thrombocytopenia, immune reconstitution syndrome, autoimmune disorders. Fat redistribution, hyperbilirubinemia.

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12. 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
13. www.uptodate.com: Indinavir: Drug information
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