

Prior Authorization DRUG Guidelines

CRIXIVAN (Indinavir)

Effective Date: 1/28/14

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

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2/2/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

NOTE: Indinavir is either no longer administered or rarely used because of poor efficacy and/or toxicity.

This drug, in addition to other protease inhibitors such as fosamprenavir, nelfinavir, saquinavir, and tipranavir are avoided when possible due to high rates of hepatotoxicity and/or other serious side effects. (SOURCE: UpToDate)

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 $\frac{1}{2}$ the standard dose plus increase indinavir to 1000 mg every 8 hours

Dosing: Pediatric:

HIV: Children 4-15 years (investigational): 500 mg/m² 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.

References:

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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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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
14. www.epocrates.com: Crixivan (indinavir) Drug information

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