
Prior Authorization DRUG Guidelines

REYATAZ (Atazanavir)

Effective Date: 7/28/05

Date Developed: 7/11/05 by C. Wilhelmy MD

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Reyataz is an Antiretroviral Agent, Protease Inhibitor. It inhibits the HIV-1 protease which prevents cleavage of the gag-pol polyprotein resulting in the production of immature, noninfectious virus.

Pre-Authorization Criteria:

Reyataz is used in the treatment of HIV-1 infections in combination with at least two other antiretroviral agents. In patients with prior virologic failure, coadministration with ritonavir is recommended.

VCHCP requires that Reyataz be prescribed by an Immunology Clinic physician or a specialist in Infectious Disease.

DOSING: ADULTS — Treatment of HIV-1 infection:

Antiretroviral-naive patients: 400 mg once daily; administer with food.

Antiretroviral-experienced patients: 300 mg once daily plus ritonavir 100 mg once daily; administer with food.

Coadministration with efavirenz:

Antiretroviral-naive patients: It is recommended that atazanavir 300 mg plus ritonavir 100 mg be given with efavirenz 600 mg (all as a single daily dose); administer with food.

Antiretroviral-experienced patients: Recommendations have not been established.

Coadministration with didanosine buffered formulations: Administer atazanavir 2 hours before or 1 hour after didanosine buffered formulations.

Coadministration with tenofovir: The manufacturer recommends that atazanavir 300 mg plus ritonavir 100 mg be given with tenofovir 300 mg (all as a single daily dose); administer with food.

DOSING: RENAL IMPAIRMENT — No recommendation for dosage adjustment.

DOSING: HEPATIC IMPAIRMENT

Moderate hepatic insufficiency (Child-Pugh Class B): Reduce dose to 300 mg once daily.

Severe hepatic insufficiency (Child-Pugh Class C): Avoid use.

DOSAGE FORMS — Capsules, as sulfate: 100 mg, 150 mg, 200 mg

ADMINISTRATION — Administer with food.

ADVERSE REACTIONS SIGNIFICANT — Protease inhibitors cause dyslipidemia which includes elevated cholesterol and triglycerides and a redistribution of body fat centrally to cause increased abdominal girth, buffalo hump, facial atrophy, and breast enlargement. These agents also cause hyperglycemia.

WARNINGS / PRECAUTIONS — Atazanavir is hepatically metabolized and has multiple drug interactions. A listing of medications that should not be used is available with each bottle and patients should be provided with this information. Use caution with medications metabolized by CYP3A4 and/or UGT1A1 (many are contraindicated). Additional CYP3A4 substrates include calcium channel blockers, immunosuppressants, and sildenafil.

Atazanavir may prolong PR interval, use with caution in patients with pre-existing conduction abnormalities or with medications which prolong AV conduction (dosage adjustment required with some agents); rare cases of AV block have been reported. May exacerbate pre-existing hepatic dysfunction; use caution in patients with hepatitis B or C or in patients with cirrhosis. Asymptomatic elevations in bilirubin (unconjugated) occur commonly during therapy with atazanavir; consider alternative therapy if bilirubin is >5 times ULN. Evaluate alternative etiologies if transaminase elevations also occur.

Use with caution in patients with hemophilia A or B; increased bleeding during protease inhibitor therapy has been reported. Changes in glucose tolerance, hyperglycemia, exacerbation of diabetes, DKA, and new-onset diabetes mellitus have been reported in patients receiving protease inhibitors. May be associated with fat redistribution (buffalo hump, increased abdominal girth, breast engorgement, facial atrophy). Atazanavir has been associated with development of rash (median onset 8 weeks); if mild-moderate, treatment may be continued (rash may resolve); discontinue therapy in cases of severe rash. Optimal dosing in pediatric patients has not been established; do not use in children <3 months of age due to potential for kernicterus.

MONITORING PARAMETERS — Viral load, CD4, serum glucose; liver function tests, bilirubin.

DRUG INTERACTIONS — Multiple drug-drug interactions have been reported, consult Reyataz website for more information.

Some products that may interact with this drug include: drugs for irregular heartbeat (such as amiodarone, quinidine), beta-blockers (such as propranolol, atenolol, metoprolol), certain chemotherapy drugs (dasatinib, lapatinib, sunitinib, temsirolimus), digoxin, eletriptan, eplerenone, etravirine, warfarin.

Other medications can affect the removal of atazanavir from the body, which may affect how atazanavir works. Examples include St. John's wort, rifamycins (such as rifabutin), certain anti-seizure drugs (carbamazepine, phenobarbital), other HIV drugs (such as delavirdine, indinavir, ritonavir, tenofovir), among others.

PREGNANCY RISK FACTOR — B

PREGNANCY IMPLICATIONS — Teratogenic effects not observed in animal studies. It is not known if atazanavir crosses the human placenta. Pregnancy and protease inhibitors are both associated with an increased risk of hyperglycemia. Glucose levels should be closely monitored. It is not known if atazanavir will exacerbate hyperbilirubinemia in neonates. Health professionals are encouraged to contact the antiretroviral pregnancy registry to monitor outcomes of pregnant women exposed to antiretroviral medications (1-800-258-4263 or www.APRegistry.com).

LACTATION — Excretion in breast milk unknown/not recommended.

BREAST-FEEDING CONSIDERATIONS — HIV-infected mothers are discouraged from breast-feeding to decrease potential transmission of HIV.

PATIENT EDUCATION — This drug may interact with many medications. Check with prescriber before taking any medication, including OTC and herbal medicines. This drug is not a cure for HIV and has not been shown to reduce the risk of transmitting HIV to others. Do not miss doses. If you miss a dose, take as soon as possible and return to your regular schedule (never take a double dose). Frequent blood tests may be required with prolonged therapy. May cause nausea or vomiting (small, frequent meals, frequent mouth care, chewing gum, or sucking lozenges may help). Report rash; difficulty breathing; CNS changes (migraine, confusion, suicidal ideation); muscular or skeletal pain, weakness, or tremors; or other adverse reactions.

REFERENCES

1. Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States. June 23 2004. Available at: <http://www.aidsinfo.nih.gov>. Accessed July 1; 2004.
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2. Reyataz internet site accessed July 11, 2005 at <http://www.reyataz.com/>
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