VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

LEXIVA (fosamprenavir)

Effective Date: 7/28/05
Date Developed: 7/11/05 by C. Wilhelmy MD
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Lexiva is an Antiretroviral Agent, Protease Inhibitor. Fosamprenavir is rapidly and almost completely converted to amprenavir in vivo. Amprenavir binds to the protease activity site and inhibits the activity of the enzyme. HIV protease is required for the cleavage of viral polyprotein precursors into individual functional proteins found in infectious HIV. Inhibition prevents cleavage of these polyproteins, resulting in the formation of immature, noninfectious viral particles.

Pre-Authorization Criteria:

Lexiva is used in the treatment of HIV infections in combination with at least two other antiretroviral agents.

VCHCP requires that Lexiva be prescribed by an Infectious Disease Physician or Physician with current American Academy of HIV Medicine (AAHIVM) Certification.

DOSING: ADULTS
HIV infection, therapy-naive patients: Oral: 1400 mg twice daily (without ritonavir)
Dosage adjustments when administered in combination therapy:
Concurrent therapy with ritonavir: Adjustments necessary for both agents:
Fosamprenavir 1400 mg plus ritonavir 200 mg once daily or
Fosamprenavir 700 mg plus ritonavir 100 mg twice daily
Concurrent therapy with efavirenz and ritonavir: Fosamprenavir 1400 mg daily plus ritonavir 300 mg once daily; no dosage adjustment recommended for twice-daily regimen

HIV infection, protease inhibitor-experienced patients: Oral: Fosamprenavir 700 mg plus ritonavir 100 mg twice daily. Note: Once-daily administration is not recommended in protease inhibitor-experienced patients.

DOSING: RENAL IMPAIRMENT — No dosage adjustment required.

DOSING: HEPATIC IMPAIRMENT

Note: No recommendations are available for dosage adjustment in patients receiving ritonavir and fosamprenavir.

Mild-moderate impairment (Child-Pugh score 5-8): Reduce dosage of fosamprenavir to 700 mg twice daily (without concurrent ritonavir)

Severe impairment: Use is not recommended.

DOSAGE FORMS — Tablet, as calcium: 700 mg; Oral Suspension 50 mg/ml

Adults should take the liquid form without food. Children (younger than 19 years) should take the liquid form with food. If vomiting occurs within 30 minutes after dosing, the dose should be repeated.

CONTRAINDICATIONS — Hypersensitivity to amprenavir or any component of the formulation; concurrent therapy with cisapride, ergot derivatives, midazolam, pimozide, and triazolam; severe previous allergic reaction to sulfonamides

WARNINGS / PRECAUTIONS — Because of hepatic metabolism and effect on cytochrome P450 enzymes, amprenavir should be used with caution in combination with other agents metabolized by this system (see Contraindications and Drug Interactions). Avoid concurrent administration of lovastatin or simvastatin (may increase the risk of rhabdomyolysis). Avoid use of hormonal contraceptives, rifampin, and/or St John's wort (may lead to loss of virologic response and/or resistance). Use with caution in patients with diabetes mellitus, sulfonamide allergy, hepatic impairment, or hemophilia. Redistribution of fat may occur (eg, buffalo hump, peripheral wasting, cushingoid appearance). Dosage adjustment is required for combination therapies (ritonavir and/or efavirenz); in addition, the risk of hyperlipidemia may be increased during concurrent therapy. Discontinue therapy in severe or dermatologic reactions or when a moderate rash is accompanied by systemic symptoms. Numerous drug-drug interactions have been reported; consult Lexiva website for details.

PREGNANCY RISK FACTOR — C

PREGNANCY IMPLICATIONS — It is not known if amprenavir crosses the human placenta and there are no clinical studies currently underway to evaluate its use in pregnant women. Pregnancy and protease inhibitors are both associated with an increased risk of hyperglycemia. Glucose levels should be closely monitored. 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/contraindicated

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

REFERENCES
1. Falcoz, C, Jenkins, JM, Bye, C, et al. Pharmacokinetics of GW433908, A Prodrug of Amprenavir, in Healthy Male Volunteers. Clin Pharmacol 2002; 42:887.
2. 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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3. Lexiva interent site accessed July 11, 2005 http://lexiva.com/

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