INTEROFFICE MEMORANDUM

DATE: March 9, 2015

TO: County Health Department Directors/Administrators
County Health Department Medical/Nursing Directors
County Health Department HIV/AIDS Medical Providers
County Health Department AIDS Drug Assistance Program Managers
County Health Department Pharmacists
HIV/AIDS Program Coordinators

FROM: Anna M. Likos, MD, MPH
Division Director, Disease Control and Health Protection

SUBJECT: Addition of Evotaz™ (Atazanavir/Cobicistat) to the AIDS Drug Assistance Program (ADAP) Formulary

INFORMATIONAL ONLY: New Antiretroviral Approved by FDA for Use in Treatment of HIV-1 Infection

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Evotaz™ (atazanavir 300mg/ cobicistat 150mg) tablet has been added to the ADAP Formulary.

On January 29, 2015, the U.S. Food and Drug Administration (FDA) announced the approval of Evotaz indicated for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in adults.

Evotaz is a fixed-dose combination product containing 300 mg of atazanavir (Reyataz®), an HIV-1 protease inhibitor and 150 mg of cobicistat, a pharmacokinetic enhancer. In treatment naïve and experienced adults, the recommended dose of Evotaz is one oral tablet taken once daily with food.

Evotaz is the first and only protease inhibitor pharmacoenhanced by cobicistat that is supported by comparative Phase III clinical trial data (Gilead Sciences, Inc.'s Study 114). The safety and efficacy of atazanavir coadministered with cobicistat were evaluated in a randomized, double-blind, active-controlled trial (Study 114) in HIV-1 infected treatment-naive subjects with baseline estimated creatinine clearance above 70 mL/min (N=692). In Study 114, subjects were randomized in a 1:1 ratio to receive either atazanavir 300 mg coadministered with cobicistat 150 mg once daily or atazanavir 300 mg coadministered with ritonavir 100 mg once daily. Low rates of virologic failure (HIV-1 RNA ≥50 copies/mL: 6% Evotaz arm; 4% Reyataz/ritonavir arm) were observed at 48 weeks, making Evotaz the only protease inhibitor pharmacoenhanced with cobicistat with virologic failure rates as low as 6%. Evotaz demonstrated a safety profile comparable to Reyataz/ritonavir.

The most common moderate to severe adverse events in the Evotaz arm and Reyataz/ritonavir arm were: rash (5%, 4%); jaundice (5%, 3%); ocular iterus (3%, 1%); nausea (2%, 2%). There were similar low rates of discontinuation due to adverse events (AEs) with Evotaz as compared to Reyataz/ritonavir (7% and 7%, respectively).

The use of Evotaz in patients who have previously received HIV medication should be guided by their baseline resistance to protease inhibitors.

Evotaz is contraindicated in patients with previously demonstrated clinically significant hypersensitivity (e.g., Stevens-Johnson syndrome, erythema multiforme, or toxic skin eruptions) to any of the product components of this product and when coadministered with certain drugs (e.g., rifampin, irinotecan, triazolam) for which altered plasma concentrations are associated with serious and/or life-threatening events or loss of therapeutic effect.

For full prescribing information, please follow link: *http://packageinserts.bms.com/pi/pi_evotaz.pdf*

Please direct any questions to Jeffrey Beal, MD, AAHIVS, Medical Director, HIV/AIDS Section at (850) 519-3734 or by email at *Jeff.Beal@flhealth.gov*.

JB/dt

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