Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Vision: To be the **Healthiest State** in the Nation

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

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 Prezcobix™ (800 mg of Darunavir and 150 mg of 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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Prezcobix™ (darunavir 800mg/cobicistat 150mg) tablet has been added to the ADAP Formulary.

On January 29, 2015, the US Food and Drug Administration (FDA) announced the approval of Prezcobix™ a human immunodeficiency virus (HIV-1) protease inhibitor combined with a CYP3A4 inhibitor for the treatment of HIV-1 in combination with other antiretroviral agents for treatment-naïve and treatment-experienced adults with no darunavir resistance-associated substitutions.

Prezcobix™ is a once daily, fixed-dose antiretroviral combination tablet containing 800 mg of darunavir, marketed as Prezista® in the United States, and 150 mg of cobicistat, a pharmacokinetic enhancer or "boosting agent", developed and marketed as Tybost®, Gilead Sciences, Inc., taken orally with other antiretroviral medications.

The efficacy of Prezcobix™ is based on clinical trials of darunavir co-administered with ritonavir and pharmacokinetic trials showing similar exposures of darunavir when boosted with cobicistat compared to ritonavir boosted darunavir. One single arm clinical trial was conducted with darunavir 800mg and cobicistat 150 mg administered as single entities in 313 HIV-infected subjects. Adverse reactions evaluated through week 24 did not differ substantially from those reported in clinical trials with darunavir co-administered with ritonavir.

The recommended dosage of Prezcobix™ is one tablet taken once daily orally with food. The most common adverse reactions occurring in greater than or equal to 5% with a severity of greater than or equal to Grade 2 were diarrhea, nausea, rash, headache, abdominal pain and vomiting.

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Prezcobix™ may cause a drug-induced hepatitis, skin reactions including Stevens-Johnson Syndrome, toxic epidermal necrolysis or eosinophilic drug rash. Cobicistat may cause a modest increase in serum creatinine and if a confirmed increase occurs of greater than 0.4 mg/dL from baseline, closely monitor renal status. When Prezcobix™ is used in combination with tenofovir disoproxil fumarate cases of acute renal failure and Fanconi syndrome has been reported.

Coadministration of Prezcobix™ with other drugs can result in significant drug interactions as both cobicistat and darunavir inhibit CYP3A and CYP2D6 and cobicistat inhibits the following transporters: p-glycoprotein, BCRP, OATP1B1 or OATP1B3. Consult the full prescribing information prior to and during therapy.

Prezcobix™ is a product of Janssen Pharmaceuticals.

For full Prezcobix™ prescribing information, please follow link *http://www./prezcobix/prescribing-information.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

cc: Celeste Philip, MD, MPH, Deputy Secretary for Health
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