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 Tybost® (Cobicistat) to the AIDS Drug Assistance Program (ADAP) Formulary

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

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Tybost® (cobicistat) 150 mg tablet has been added to the ADAP Formulary.

On September 24, 2014, the US Food and Drug Administration (FDA) approved Tybost® (cobicistat), a product of Gilead Sciences Inc., for use in treatment of HIV-1 infection.

Tybost® is a pharmacokinetic enhancer (a drug used to boost other medications in the blood to make them more effective). Tybost® was developed to be used in combination with other drugs - for use in combination with either Reyataz® (atazanavir) or Prezista® (darunavir), and as a component of the fixed-dose combination tablets Stribild®, Evotaz®, and Prezcobix®.

Tybost® is not active against HIV. It works by inhibiting an enzyme called CYP3A4 that is responsible for metabolizing certain medications, including several HIV drugs. This helps boost the effectiveness of these drugs, while allowing fewer pills or doses on a daily basis.

The recommended dosage for Tybost® is a 150 mg tablet taken orally once daily and must be coadministered with atazanavir (300 mg orally once daily) or darunavir (800 mg orally once daily), and taken with food.

- Tybost® is not interchangeable with Norvir® (ritonavir) to increase the systemic exposure of darunavir 600 mg twice daily, fosamprenavir, saquinavir, or tipranivir due to lack of exposure data.

Florida Department of Health
Division of Disease Control and Health Protection
Bureau of Communicable Diseases
4052 Bald Cypress Way, Bin A-09 • Tallahassee, FL 32399-1715
PHONE: 850/245-4334 • FAX 850/414-0038

www.FloridaHealth.gov
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh
FLICKR: HealthyFla
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- Complex or unknown mechanisms of drug interactions preclude extrapolation of ritonavir drug interactions to certain Tybost® interactions.

Tybost® decreases estimated creatinine clearance due to inhibition of tubular secretion of creatinine without affecting actual renal glomerular function. For patients with a rise in serum creatinine greater than 0.4 mg/dL from baseline, monitor closely for renal safety.

If coadministered with tenofovir disoproxil fumarate, assess baseline estimated creatinine clearance, urine glucose and protein. Coadministration is not recommended if estimated creatinine clearance is less than 70 mL/min.

Contraindications: Coadministration with drugs metabolized by CYP3A4 or CYP2D6 or with drugs that induce CYP3A can result in altered drug concentrations. Consult full prescribing information to evaluate drug-to-drug interactions prior to and during therapy.

Use in Specific Populations: Pregnancy Category B: Use only if the potential benefit justifies the potential risk. Nursing mothers: HIV infected women should not breastfeed due to the potential for HIV transmission.

For full Tybost® prescribing information, please follow link ***HERE***.

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
R. S. Whisenhunt, Chief, Bureau of Communicable Disease
Marlene LaLota, MPH, Administrator, HIV/AIDS Section
Jeffrey Beal, MD, AAHIVS, Medical Director, HIV/AIDS Section
Brandon Brantley, PharmD, Chief, Bureau of Public Health Pharmacy
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