Rick Scott
Governor

FLORIDA DEPARTMENT OF HEALTH

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

INTEROFFICE MEMORANDUM

DATE: October 1, 2012

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
County Health Department HIV/AIDS Program Administrators

FROM: Jennifer Bencie, MD, MSA
Interim Director, Division of Disease Control

SUBJECT: Addition of New Antiretroviral to ADAP Formulary – Stribild™

FOR INFORMATION ONLY: New Antiretroviral

Stribild™, (elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate) a Complete Once-Daily Single Tablet Regimen has been added to the ADAP Formulary.

On August 27, 2012, Stribild™, a combination product in one pill with an integrase strand transfer inhibitor (elvitegravir), and two nucleos(t)ide analog HIV-1 reverse transcriptase inhibitors (emtricitabine and tenofovir) was approved by the Food and Drug Administration for the treatment of human immunodeficiency virus type 1 (HIV 1) infection in adults who are antiretroviral treatment-naïve. This pill also contains a pharmacologic boosting agent (cobicistat) used to prolong the effect of elvitegravir. The recommended dose of Stribild™ is one tablet taken orally once daily with food.

The following points should be considered when initiating therapy with Stribild™ (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg):

Contraindicated with drugs that:

1) Are highly dependent on CYP3A for clearance as these drugs would have elevated plasma concentrations and could result in serious and/or life threatening adverse events, and
2) Strongly induce CYP3A which lowers STRIBILD which may cause loss of virologic response and possible resistance to develop.

Additionally, since cobicistat is a boosting agent that may cause modest increases in serum creatinine and modest declines in estimated creatinine clearance without affecting renal glomerular function, patients who experience a confirmed increase in serum creatinine of greater than 0.4 mg per dL from baseline should be closely monitored for renal safety.

Stribild™ has Boxed Warnings of lactic acidosis/severe hepatomegaly with steatosis and post treatment acute exacerbation of hepatitis B.

Please direct any questions to Jeffrey Beal, M.D., Medical Director, HIV/AIDS and Hepatitis Program at (850) 519-3734 or by email at Jeff_Beal@doh.state.fl.us.

JB/dt
Attachment

cc: John H. Armstrong, MD, FACS, FCCP, State Surgeon General
Dennis Cookro, MD, MPH, Deputy Secretary for Health
Sherry Riley, Program Administrator, Bureau of Communicable Diseases
Brandon E. Brantley, Pharm.D., C.Ph., LSS GB, Chief, Bureau of Public Health Pharmacy
Jeffrey Beal, M.D., AAHIVS, Medical Director, HIV/AIDS and Hepatitis Program
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