FLORIDA DEPARTMENT OF HEALTH

Rick Scott
Governor

H. Frank Farmer, Jr., M.D., PhD, FACP
State Surgeon General

INTEROFFICE MEMORANDUM

DATE: November 17, 2011

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: Julia Gill, Ph.D., M.P.H.
Director, Division of Disease Control

SUBJECT: Addition to ADAP Formulary – Emtricitabine/Rilpivirine/Tenofovir DF (Complera™)

FOR INFORMATION ONLY: New Antiretroviral

Emtricitabine/Rilpivirine/Tenofovir DF (Complera™) has been added to the ADAP Formulary.

On August 10, 2011, Complera™, a fixed dose combination (FDC) drug product containing emtricitabine/rilpivirine/tenofovir DF (FTC/RPV/TDF) was approved by the Food and Drug Administration (FDA) for the treatment of HIV type 1 (HIV-1) infection in antiretroviral treatment naïve adult patients. The recommended dose of Complera™ is one tablet, containing 200mg emtricitabine/25mg rilpivirine/300mg tenofovir once daily, taken orally with a meal.

Complera™ is a complete regimen for treatment of HIV infection in treatment naïve patients because it contains a Nonnucleoside Reverse Transcriptase Inhibitor (NNRTI), i.e., rilpivirine (Edurant™), and two Nucleoside Reverse Transcriptase Inhibitors (NRTIs), i.e., emtricitabine and tenofovir DF (Truvada®).

The following points should be considered when initiating therapy with emtricitabine/rilpivirine/tenofovir DF (Complera™):

- More rilpivirine (Edurant™) treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure compared to subjects with HIV-1 RNA less than 100,000 copies/mL at the start of therapy

- The observed virologic failure rate in rilpivirine (Edurant™) treated subjects conferred a higher rate of overall treatment resistance and cross-resistance to the NNRTI class compared to efavirenz (Sustiva®)

- More subjects treated with rilpivirine (Edurant™) developed lamivudine/emtricitabine (Truvada®) associated resistance compared to efavirenz (Sustiva®)

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

JG/jb
Enclosures

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Ryan White Title II (Part B) Consortia Chairs