



Rick Scott
Governor

H. Frank Farmer, Jr., MD, PhD, FACP
State Surgeon General

INTEROFFICE MEMORANDUM

DATE: July 18, 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: Douglas A. Holt, M.D.
Acting Deputy Secretary for Health *[Signature]*
Acting Director, Office of Minority Health

SUBJECT: Addition to ADAP Formulary – Rilpivirine (Edurant™)

FOR INFORMATION ONLY: New Antiretroviral

Rilpivirine (Edurant™) Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) has been added to the ADAP Formulary.

On May 20, 2011, the Food and Drug Administration (FDA) approved rilpivirine (Edurant™), a new NNRTI for the treatment of HIV in antiretroviral (ARV) naïve patients. Rilpivirine (Edurant™) was FDA approved based upon clinical trial evidence in treatment naïve patients comparing Edurant™ to efavirenz (Sustiva®). In the clinical trial, more Edurant™ treated patients with an HIV viral load greater than 100,000 copies/ml at the start of therapy experienced virologic failure compared to those with less than 100,000 copies/ml at the start of therapy. In those patients with a viral load less than 100,000 copies/ml, the failure rate was equal to efavirenz (Sustiva®).

The recommended adult dosage is one 25 mg tablet taken orally once daily with a meal. It is FDA approved for use in combination with other antiretroviral agents in treatment-naïve adult patients. The most common side effects were mild and included depression, difficulty sleeping, headache and rash.

Rilpivirine (Edurant™) is Pregnancy Category B (no toxicity in animal studies, but no human data to date – use in pregnancy only if the benefit outweighs the risk). Safety and effectiveness in pediatric patients have not been established.

Rilpivirine (Edurant™) is a product of Tibotec Therapeutics; see complete prescribing information for additional precautions (attached).

Addition to ADAP Formulary
Page Two
July 18, 2011

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

cc: Douglas A. Holt, M.D., Interim Deputy Secretary for Health and
Director, Office of Minority Health
Thomas Liberti, Chief, Bureau of HIV/AIDS
Jasper W. Watkins III, M.S.A., C.Ph, R.Ph, N.P., B.C.N.P.
Chief, Bureau of Statewide Pharmaceutical Services
Ryan White Title I (Part A) Planning Committees
Ryan White Title II (Part B) Consortia Chairs