From:	Romero, Javier E
To:	Wall, Daniel (OMB); Valle-Schwenk, Carla J. (OMB); Dr. Robert A. Ladner; Francisco Sastre
Cc:	Zayas, Maribel A; Dubuisson, Germa; Coles, Sybille
Subject:	FW: Addition of Descovy® (emtricitabine and tenofovir alafenamide) to the Florida AIDS Drug Assistance Program (ADAP) Formulary
Date:	Friday, May 27, 2016 11:11:54 AM

FYI
ADAP Formulary Expansion (2/2)

Thanks.

Javier Romero, MD, MPH / ADAP-Miami
Florida Department of Health in Miami-Dade County
ADAP Program Manager
Email: Javier.Romero@flhealth.gov
Phone: (305) 643-7404
Mailing Address: 2515 W Flagler St. MIAMI, FL 33135

From: Farlin, Annie E **On Behalf Of** Beal, Jeff A
Sent: Friday, May 27, 2016 11:06 AM
To: DL HSD AIDS HIV CARE PROVIDERS <DLHSDAIDSHIVCAREPROVIDERS@flhealth.gov>
Subject: Addition of Descovy® (emtricitabine and tenofovir alafenamide) to the Florida AIDS Drug Assistance Program (ADAP) Formulary

INFORMATIONAL ONLY: New Medication Approved by FDA for Use in Treatment of Human Immunodeficiency Virus-1 (HIV-1) has been added to the Florida ADAP Formulary.

Descovy® [emtricitabine (FTC) 200 mg I tenofovir alafenamide (TAF) 25 mg], a new nucleoside analog reverse transcriptase inhibitor (NRTI) has been added to the ADAP Formulary for use in combination with other antiretroviral (ARV) medications for the treatment of HIV-1 infection.

On April 4, 2016, the US Food and Drug Administration (FDA) approved Descovy® (emtricitabine and tenofovir alafenamide [F/TAF]), a product of Gilead Sciences Inc., as an NRTI to be used in combination with other ARVs for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older . Descovy® is not indicated for use as pre-exposure prophylaxis (PrEP).

The FDA approval of Descovy® is based on a relative bioavailability trial. This trial demonstrated FTC and TAF exposures were similar between Descovy® and Genvoya® (elvitegravir/cobicistat/FTC/T AF). Safety and efficacy of FTC and TAF was established previously in clinical trials with Genvoya®, and therefore a clinical trial was not required of Descovy.

Descovy® is taken orally once daily with or without food. It is intended for adults

and pediatric patients 12 years of age and older with a body weight of at least 35 kg as well as creatinine clearance greater than or equal to 30 ml per minute.

The most common adverse reaction observed with Descovy® is nausea.

Prior to and while on Descovy®, the patient's estimated creatinine clearance (CrCI), urine glucose, and urine protein should be assessed. Do not administer Descovy® if CrCI is less than 30 ml/min. Also, the patient should be tested for hepatitis B virus infection.

The safety warning for Descovy® relates to the potential for lactic acidosis and severe hepatomegaly with steatosis, as well as acute exacerbation of hepatitis B upon discontinuation of Descovy®. Descovy® is not approved as a treatment for chronic hepatitis B virus (HBV) infection.

There are no contraindications to taking Descovy®. As with all antiretroviral medications, providers should evaluate for drug interactions before prescribing . Potentially significant drug interactions resulting in reduced tenofovir alafenamide levels can occur with tipranavir/ritonavir, anticonvulsants, antimycobacterials, and St. John's wort.

For full Descovy® 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.

Kind regards,

Jimmy R. LLaque, Director
AIDS Drug Assistance Program (ADAP)
HIV/AIDS Section, Patient Care
Bureau of Communicable Diseases
Division of Disease Control & Health Protection
Florida Department of Health
☎ (850) 245-4477
www.FloridaADAP.org