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Our Mission is to protect, promote & improve the health of all people in Florida through integrated state, county, &
community efforts.

Please note: Florida has very broad public records law. Most written communication to or from state officials
regarding state business are public records available to the public and media upon request. Your e-mail
communications may therefore be subject to public disclosure.

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 (CrCl), urine glucose, and urine protein should be assessed. Do not administer Descovy® if CrCl 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
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