Valle-Schwenk, Carla J. (OMB)

From: Romero, Javier E <Javier.Romero@flhealth.gov>
Sent: Friday, May 27, 2016 11:13 AM
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 Odefsey® (emtricitabine, rilpivirine, and tenofovir alafenamide) to the Florida AIDS Drug Assistance Program (ADAP) Formulary

FYI
ADAP Formulary expansion (1/2)

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 11:04 AM
To: DL HSD AIDS HIV CARE PROVIDERS <DLHSDAIDSHIVCAREPROVIDERS@flhealth.gov>
Subject: Addition of Odefsey® (emtricitabine, rilpivirine, 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.

Odefsey® (emtricitabine 200mg I rilpivirine 25mg I tenofovir alafenamide 25mg), a new single-tablet regimen has been added to the Florida ADAP Formulary for the treatment of HIV-1 infection.

On March 1, 2016, the US Food and Drug Administration (FDA) approved Odefsey® (emtricitabine, rilpivirine, and tenofovir alafenamide [R/F/TAF]), a product of Gilead Sciences Inc., as a complete regimen for the treatment of HIV-1 infection.

Odefsey® is intended for patients 12 years of age and older with a history of HIV-1 RNA less than/equal to 100,000 copies/ml. Odefsey® can also replace a current HIV medication regimen in individuals who are virologically suppressed with HIV-1 RNA at less than 50 copies/ml for at least six months with no history of treatment failure or resistance to any of the components that make up Odefsey®.

Odefsey® is the second tenofovir alafenamide-based regimen to receive FDA approval and is the smallest single-tablet complete antiretroviral (ARV) regimen on the market for the treatment of HIV. TAF has

demonstrated high antiviral efficacy similar to that of tenofovir disoproxil fumarate (TDF), at a much lower dose and has demonstrated improved renal and bone health in clinical studies. Data shows that TAF is much more efficient in entering cells than TDF and can therefore be given at a much lower dose with 90 percent less tenofovir in the bloodstream according to Gilead.

The recommended dosage for Odefsey® is one tablet taken orally once daily and should be taken with a meal.

The most common adverse reactions observed with Odefsey® are depressive disorders, insomnia, headache and nausea.

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

Odefsey® safety warning relates to the potential for lactic acidosis, and severe hepatomegaly with steatosis as well as acute exacerbation of hepatitis B on discontinuation if other anti-hepatitis
B therapy is not initiated. Odefsey® is not approved as a treatment for chronic hepatitis B virus (HBV) infection.

Contraindications to taking Odefsey® include coadministration with medications that increase gastric pH which may result in significant decreases in rilpivirine plasma concentration and thus potential resultant resistance could occur. Drugs that induce CYP3A may as well result in loss of efficacy and potential resistance to rilpivirine.

For full Odefsey® 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