From: Valle-Schwenk, Carla J. (OMB)
To: Valle-Schwenk, Carla J. (OMB)
Subject: FW: Addition to AIDS Drug Assistance Program (ADAP) Formulary – Triumeq®
Date: Monday, November 17, 2014 5:52:47 PM

Begin forwarded message:

From: "Wells, Lorraine" <Lorraine.Wells@flhealth.gov>
Date: October 29, 2014 at 5:04:00 PM EDT

SUBJECT: Addition to AIDS Drug Assistance Program (ADAP) Formulary – Triumeq®

Triumeq® (abacavir 600mg, dolutegravir 50mg, and lamivudine 300mg) has been added to the ADAP Formulary. Pronunciation: TRY-u-meck.

On August 22, 2014, the US Food and Drug Administration (FDA) approved Triumeq® tablets for the treatment of HIV-1 infection. Triumeq® is ViiV Healthcare's first dolutegravir-based fixed-dose combination, offering many people living with HIV the option of a single-pill regimen that combines the integrase strand inhibitor (INSTI) dolutegravir (Tivicay®), with the nucleoside reverse transcriptase inhibitors (NRTIs) abacavir (Ziagen®) and lamivudine (Epivir®).

Triumeq® alone is not recommended for use in patients with a current or past history of resistance to any components of Triumeq®. Triumeq® alone is not recommended in patients with resistance-associated integrase substitutions or clinically suspected integrase strand transfer inhibitor (INSTI) resistance since the dose of dolutegravir in Triumeq® is insufficient in these subpopulations.

Products containing abacavir should not be used in patients known to carry the HLA-B*5701 allele, therefore, before initiating treatment with abacavir-containing products, screening for the presence of the genetic marker, HLA-B*5701, should be performed in any HIV-infected patient, irrespective of racial origin.

Dosage for adults is one tablet taken once daily (without regard to meals). If Triumeq® is dosed with efavirenz, fosamprenavir/ritonavir, tipranavir/ritonavir, or rifampin, an additional 50-mg dose of dolutegravir (separated from Triumeq® by 12 hours) should be taken.

In those receiving Triumeq®, the most commonly reported adverse reactions of at least moderate intensity and incidence at 2-3% were insomnia, headache and fatigue. Triumeq® carries the black box warnings of hypersensitivity reaction, lactic acidosis and severe hepatomegaly, and exacerbations of hepatitis B related to the coformulated NRTIs.

CONTRAINDICATIONS

- Presence of HLA-B*5701 allele
- Previous hypersensitivity reaction to abacavir, dolutegravir, or lamivudine
- Coadministration with Tikosyn® (dofetilide)
- Moderate or severe hepatic impairment

USE IN SPECIFIC POPULATIONS

- Pregnancy: Triumeq® should be used during pregnancy only if the potential benefit justifies the potential risk.
- Nursing mothers: Breastfeeding is not recommended due to the potential for HIV transmission.
- Triumeq® is not recommended in patients with creatinine clearance less than 50mL per min.
- If a dose reduction of abacavir (a component of Triumeq®) is required for patients with mild hepatic impairment, then the individual components should be used.

For full Triumeqâ prescribing information, please follow link HERE.
[sic] Or, copy and paste the following link in your browser --
http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205551s000lbl.pdf?utm_source=CareLink+%28Special+Announcement%3A+Triumeq%29&utm_campaign=SA%3A+8%2F28%2F2014&utm_medium=email

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*.

Lorraine Wells

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