



CALIFORNIA AIDS DRUG ASSISTANCE PROGRAM (ADAP) CLINICAL UPDATE

FIRST QUARTER 2007

ADAP CLINICAL UPDATE

Welcome to the first edition of the California Department of Health Services, Office of AIDS (OA), ADAP Clinical Update. This newsletter is designed to be an informative, quick reference for current ADAP related topics.

I am Stephen Berk, Pharmaceutical Consultant for ADAP. On a regular basis I plan to provide information on the U.S. Food and Drug Administration (FDA) alerts related to HIV/AIDS medications, medications in the HIV/AIDS treatment pipeline, and updates on ADAP policy.

You may have topics that you would like covered. I would be happy to try to include your suggestion in a future newsletter. Please contact me with questions, concerns, or suggestions at (916) 449-5988 or e-mail sberk@dhs.ca.gov.

DRUG SAFETY

Information on the medications for treating HIV/AIDS and related conditions is changing rapidly. FDA offers a Listserv that will automatically notify providers when information is updated.

Since the beginning of 2007, FDA has released three notices concerning the safety or labeling changes related to medications of interest in the treatment of HIV/AIDS.

The first two notices, released on January 1, 2007, addressed Fuzeon® (enfuvirtide) and Sustiva® (efavirenz).

Additions to the Fuzeon® product label were to include a description of nerve bundle pain, hematoma, and cautionary wording regarding Biojector use in patients with coagulopathy.

The dosage and administration section of the package insert was changed to include advising against injection of Fuzeon® near any anatomical areas where large nerves course close to the skin, skin abnormalities including surgical scars, tattoos, or burn sites.

The Sustiva® package insert was updated to include drug-drug interaction information regarding the coadministration with rifampin, diltiazem, itraconazole, voriconazole, atorvastatin, pravastatin, simvastatin, pimozone, and bepredil.

Sustiva's® dosage and administration section was specifically updated to address dosing information when the medication is coadministered with voriconazole. The maintenance dose of voriconazole should be decreased to 400mg every 12 hours and the Sustiva® dosed should be decreased to 300mg once daily. Note: Sustiva® tablets should not be broken.

The third FDA notice this year addressed the use of Baraclude® (entecavir) in co-infected individuals not currently receiving highly active antiretroviral therapy. Providers are advised that the risk of

developing HIV resistance cannot be excluded in these situations based on current information.

For more information on these and other FDA notices, you can visit the FDA HIV/AIDS Listserve Web Site at: www.fda.gov/oashi/aids/listserve/archive.html.

FORMULARY UPDATE

Recently, several medications were added to the ADAP formulary. The primary goal of ADAP is to provide antiretrovirals for treatment of HIV. However, the ADAP formulary also contains medications to manage side effects of antiretrovirals as well as medications for opportunistic infections.

The latest additions to the ADAP formulary are:

Caspofungin	Voriconazole
Dextroamphetamine	Methylphenidate
Phenytoin	Metformin
Pioglitazone	Glucovance®
Mirtazapine	Levofloxacin
Linezolid	Rosuvastatin
Fenofibrate	Aripiprazole
Ziprasidone	

For some of the above medications, only specific strengths or dosage forms may be covered. You can verify drug coverage by calling Public Health Service Bureau (PHSB) at (888) 311-7632.

PIPELINE MEDICATIONS

At the 14th Conference on Retroviruses and Opportunistic Infections (CROI), researchers presented the latest data on three experimental antiretroviral drugs that work by new mechanisms:

- Merck integrase inhibitor raltegravir (formerly MK-0518). Raltegravir targets the integrase enzyme. By blocking integrase, raltegravir prevents the insertion of HIV DNA into the human DNA genome. This effectively blocks HIV's ability to replicate. This medication is currently offered through an Expanded Access Program (EAP).
- Gilead's integrase inhibitor elvitegravir (GS-9137). Gilead's product is similar to Merck's in that it targets the integrase enzyme to prevent HIV replication.
- Pfizer CCR5 antagonist maraviroc. Maraviroc blocks viral entry into the human cells by binding to the chemokine receptor 5 co-receptor located on the surface of the CD4 cell. The mechanism prevents HIV from entering target cells, thereby, preventing the initiation of HIV's replication cycle. HIV can either use the CCR5 pathway for entry into the CD4 cell or the CXCR4 pathway. Maraviroc will only be effective in clients with HIV that utilizes the CCR5 pathway. There will be an assay available to identify the "tropism" that the client's virus exhibits, predicting response to the new medication. This medication is currently offered through an EAP.

Information regarding an experimental NNRTI was presented at the conference:

- Tibotec rilpivirine (TMC-278); 48-week data from a Phase II study showed comparable efficacy to Sustiva® (when combined with Truvada® or Combivir®).

For more information on CROI 2007 visit AIDSMEDES.Com Web site at:

www.aidsmeds.com/archive/2007_Feb_196_1.html.

PHARMACY SYRINGE SALES

Senate Bill 1159 was signed by Governor Arnold Schwarzenegger on September 20, 2004, and went into effect on January 1, 2005. The law allows a city or county to create a Disease Prevention Demonstration Project (DPDP), a collaboration between pharmacies and local and state health agencies. DPDP authorizes pharmacists in licensed pharmacies, who have registered with their local health department, to sell ten or fewer hypodermic needles or syringes for human use without a prescription. Some of the provisions of the law are:

- Eliminated requirement to keep log of syringe sales (any sales not just DPDP).
- Decriminalizes possession of ten or fewer syringes obtained from authorized source.
- Carry syringes "containerized for safe disposal" and these syringes cannot be considered as illegal drug paraphernalia.
- Sunsets in 2010 (unless extended by Legislature).

Several health departments in California have authorized the DPDP. Those health departments include:

- Contra Costa County
- Yuba County
- City of West Hollywood
- Marin County
- City and County of Los Angeles
- Santa Cruz County
- Alameda County
- City and County of San Francisco
- Yolo County

- San Mateo County
- Solano County
- Sonoma County
- Humboldt County
- Santa Barbara County
- Santa Clara County
- City of Sacramento

Contact the county health department for information.

The purpose of the legislation is to prevent the spread of HIV, hepatitis, and other blood-borne diseases among injection drug users, their sexual partners, and their children.

Pharmacies interested in participating in DPDP should contact their local health department for information.

For more general information regarding pharmacy syringe sales, feel free to contact me.

PHSB

PHSB is the pharmacy benefit management contractor for OA. PHSB processes all prescription drug claims for California ADAP. Any questions related to prescription claim processing should be address to PHSB. ADAP encourages providers to resolve billing concerns as soon as possible to prevent any unnecessary treatment interruptions. The contact number is (888) 311-7632.

E-MAIL DELIVERY

If you would like this newsletter or other communication from OA delivered by e-mail, please provide me with your e-mail address. Send responses to Sberk@dhs.ca.gov.