



Florida/Caribbean AIDS Education and Training Center

# HIV CareLink

A Newsletter for HIV/AIDS Primary Care Providers

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## ABOUT US

The Florida/Caribbean AIDS Education and Training Center provides state-of-the-art HIV education, consultation, and resource materials to health care providers in Florida, Puerto Rico and the US Virgin Islands.

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*Save the Date*  
**May 1-2, 2009**  
Rosen Centre Hotel  
Orlando, FL

*18th Annual*  
**HIV CONFERENCE**

FLORIDA/CARIBBEAN AIDS  
EDUCATION AND TRAINING CENTER

## Update on the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection

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On July 29, 2008, updated **Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection** developed by The Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children were released by the Department of Health and Human Services. The Guidelines, as well as a supplement on pediatric antiretroviral drug information is available for download at: <http://aidsinfo.nih.gov/contentfiles/PediatricGuidelines.pdf> and [http://aidsinfo.nih.gov/contentfiles/PediatricGL\\_Supl.pdf](http://aidsinfo.nih.gov/contentfiles/PediatricGL_Supl.pdf), respectively.

Updates and changes in the recommendations include the following:

### Revised preferred and alternative treatment regimen recommendations for initial therapy in HIV-infected children

Recommended antiretroviral therapy in treatment-naïve children includes the combination of 1 NNRTI plus a 2-NRTI backbone or 1 PI plus a 2-NRTI backbone.

**Preferred PI:**  
Lopinavir/ritonavir

#### Alternative PI:

- Atazanavir plus low dose ritonavir (children  $\geq 6$  yrs)
- Unboosted atazanavir added as option for children ( $\geq 13$  yrs &  $> 39$  Kg) who cannot tolerate ritonavir. Must use ritonavir boost if used with tenofovir.
- Fosamprenavir plus low dose ritonavir (children  $\geq 6$  yrs; now available in liquid formulation)
- Nelfinavir (children  $\geq 2$  yrs) added back as alternative PI-based option as formulations now meet FDA standards for ethyl methane sulfonate (EMS) content

#### NNRTI-based Regimens (with 2 NRTIs)

- No changes to recommendations except that efavirenz is not recommended due to lack of pediatric formulation and lack of pediatric efficacy and safety data

#### Preferred NNRTI:

- Efavirenz ( $\geq 3$  yrs)
- Nevirapine ( $< 3$  yrs old or who can not swallow capsules)

#### Alternative NNRTI:

Nevirapine ( $\geq 3$  yrs)

#### NRTI backbone options:

- No changes to recommended regimens

NRTI backbone options include:

#### Preferred NRTIs:

- Abacavir \* plus (lamivudine or emtricitabine)
- Didanosine plus emtricitabine
- Zidovudine plus (lamivudine or emtricitabine)
- Tenofovir plus (lamivudine or emtricitabine) (for Tanner 4 or post-pubertal adolescents only)

For more information,  
please visit our website:

[www.FCAETC.org](http://www.FCAETC.org)

To request clinical consultation, please call the  
National Clinicians' Consultation Hotline:

**1-800-933-3413**



#### Alternative NRTIs:

Zidovudine plus (abacavir\* or didanosine)

\*HLA B\*5701 genetic testing should be considered for HIV-infected children prior to initiating abacavir-based therapy, and abacavir should not be given to a child who tests positive for HLA B\*5701

#### Alternative regimens used in special circumstances include:

- Two NRTIs plus atazanavir unboosted (for treatment naïve patients  $\geq 13$  yrs and  $> 39$  kg)
- Two NRTIs plus fosamprenavir unboosted ( $\geq 2$  yrs)
- Two NRTIs plus saquinavir plus low dose ritonavir (post-pubertal adolescents)
- Zidovudine plus lamivudine plus abacavir

#### Updates in information on newly available antiretroviral therapies and new dosage information include:

- **Nevirapine (Viramune<sup>®</sup>, NVP):** Dosing based on body surface area (BSA) is recommended and avoids an abrupt change in dosing at 8 years of age. For children age  $\leq 8$  years a higher dosage may be required.
- **Lopinavir/ritonavir (Kaletra<sup>®</sup>, LPV/RTV):** Approved for children  $\geq 14$  days old in June 2008. It is available in both liquid and tablet formulations. Dosing based on BSA and weight is available. Higher doses than those listed in manufacturer's prescribing information may be needed in infants 14 days to 6 mos.
- **Atazanavir (Reyataz<sup>®</sup>, ATV):** In March 2008, ATV was approved for use in children and adolescents age  $>6$  years and dosage information is available for boosted and unboosted therapy. Higher doses may be needed in pediatric and adolescents if unboosted. In addition to capsules, a powder formulation is under study.
- **Fos-amprenavir (Lexiva<sup>®</sup>, f-APV):** In June 2007, the f-APV oral suspension was approved and dosing information is available.
- **Tipranavir (Aptivus<sup>®</sup>, TPV):** Its use boosted with ritonavir was approved in June 2008 by the FDA for use in treatment-experienced children age 2–18 years. An oral solution formulation was approved.

**New agents without sufficient pediatric data for use as initial therapy:** Insufficient pediatric pharmacokinetic and safety data is available to recommend the use of darunavir, maraviroc (CCR5 antagonist), raltegravir (integrase inhibitor), tenofovir, or etravirine (NNRTI) as components of initial regimen in children.

#### Information on resistance and coreceptor use testing

- **Antiretroviral drug resistance testing** continues to be recommended prior to initiation of therapy in all treatment-naïve children and prior to changing therapy for treatment failure.
- **Coreceptor tropism assays** should be used whenever the use of a CCR5 antagonist is being considered and might also be considered for patients who have virologic failure on CCR5-inhibitor-containing therapy.
- A compilation of the most common HIV-1 mutations selected by currently available antiretroviral agents can be accessed at <http://hiv-web.lanl.gov> or <http://hivdb.stanford.edu>.

*In addition to this update, new D.H.H.S. **Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children** are expected to be published soon. A draft of these guidelines is available at <http://aidsinfo.nih.gov/guidelines>*

**A recent HIV CareLink Issue describing these guidelines can be accessed at:**

[Opportunistic Infections in HIV-Infected Children \(PDF\)](#)