



Florida/Caribbean AIDS Education and Training Center

# HIV CareLink

A Newsletter for HIV/AIDS Primary Care Providers

## 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.

Major funding is provided by the US Public Health Service's Health Resources Services Administration (HRSA) DHHS-HAB Grant No. H4AHA00049 through the University of South Florida Center for HIV Education and Research, Michael Knox, PhD, Director.

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Volume 10 - Issue 14

December 2, 2009

## Special Bulletin: Updated Adult/Adolescent Department of Health and Human Services (DHHS) Antiretroviral Guidelines Released-December 1, 2009

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The Department of Health and Human Services released updated "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents" on December 1, 2009. These Guidelines provide updates to the prior version released in November of 2008. This edition of *HIV CareLink* summarizes the key changes to the Guidelines. The reader is encouraged to access the full Guidelines available online at [www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf](http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf).

### WHEN TO START THERAPY

- Patients need to be willing and able to commit to lifelong therapy, understand the risks and benefits of therapy, and the importance of adherence
- Patients and/or providers may elect to defer therapy based on a variety of factors and decisions should be made on a case-by-case basis
- Initiating therapy at CD4 351-500 cells/mm<sup>3</sup> is recommended
  - Panel members divided on this recommendation (55% strongly recommended and 45% were for moderate recommendation)
  - Prior DHHS recommendation was that therapy *may be considered* in asymptomatic patients with CD4 > 350 cells/mm<sup>3</sup>
- Initiating therapy when CD4 > 500 cells/mm<sup>3</sup>
  - Panel members were split with 50% in favor of starting therapy and 50% who viewed treatment as optional
- The Guidelines continue to recommend therapy initiation in the following situations:
  - All patients with a history of an AIDS-defining illness or with CD4 < 350 cells/mm<sup>3</sup>
  - Regardless of CD4 cell count in the following situations:
    - Pregnancy
    - HIV-associated nephropathy
    - Hepatitis B virus (HBV) co-infection when HBV treatment indicated

### DRUG RESISTANCE TESTING

- Genotype preferred test in treatment-naïve patients
- Genotype is the preferred test to guide therapy decisions in patients failing a first or second regimen
- Addition of phenotype to genotype is preferred for persons with known or suspected complex resistance patterns (especially with protease inhibitor complexity)

### DRUG INTERACTIONS (SELECTED UPDATES)

- Salmeterol should not be combined with ritonavir
    - Fluticasone/salmeterol has not been recommended for use with ritonavir and caution is advised with its use with unboosted protease inhibitors due to resultant increased corticosteroid adverse events. This update reinforces the need to use alternative agents unless benefit > risk.
  - Rosuvastatin levels significantly ↑ when combined with atazanavir/ritonavir (use lowest dose possible with caution)
  - Raltegravir - ↑ dose to 800 mg po bid with rifampin
  - Maraviroc 600 mg po bid if necessary to use with rifampin (use 300 mg po bid if strong CYP3A inhibitor in regimen)
- See Tables 13-15b for additional drug interaction updates

### OTHER UPDATES

- Significant updates made to sections and tables on 1) What Not to Use, 2) Management of Treatment-experienced Patients, 3) Treatment Simplification, 4) Hepatitis C Co-infection, 5) Antiretroviral-associated Adverse Effects, 6) Antiretroviral Drug Interactions, and 7) Preventing Secondary Transmission of HIV

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**1-800-933-3413**



### WHAT TO START IN TREATMENT-NAÏVE PATIENTS

- Several modifications were made to the regimen recommendations for treatment-naïve patients
  - Regimen options for treatment-naïve patients now classified as “preferred,” “alternative,” “acceptable,” “may be acceptable,” and “to be used with caution”
  - Integrase inhibitor-based regimen added as a preferred regimen option
  - Lopinavir/ritonavir (Kaletra<sup>®</sup>) and fosamprenavir/ritonavir (Lexiva<sup>®</sup>/Norvir<sup>®</sup>)-based regimens changed from preferred to alternative

### ANTIRETROVIRAL REGIMENS FOR TREATMENT-NAÏVE PATIENTS

(Adapted from Table 5a Guidelines)

**Note:** *(/r)* indicates low-dose ritonavir (Norvir<sup>®</sup>) for boosting

**PREFERRED REGIMENS** (Optimal and durable efficacy, favorable tolerability and toxicity profile, and ease of use)

**NNRTI-based Regimen:**

Efavirenz<sup>1</sup>/tenofovir/emtricitabine<sup>2</sup>

**PI-based Regimens (alphabetical):**

Atazanavir/r<sup>3</sup> + tenofovir/emtricitabine<sup>2</sup>

or

Darunavir/r + tenofovir/emtricitabine<sup>2</sup>

**Integrase inhibitor-based regimen:**

Raltegravir + tenofovir/emtricitabine<sup>2</sup>

**Preferred Regimen for Pregnant Women<sup>4</sup>:**

Lopinavir/r twice daily + zidovudine<sup>5</sup>/lamivudine<sup>2</sup>

**ALTERNATIVE REGIMENS** (Effective and tolerable but have potential disadvantages compared to preferred regimens; alternative regimen may be preferred in some patients)

**NNRTI-based Regimens (alphabetical):**

Efavirenz + [(abacavir<sup>6</sup> + lamivudine<sup>2</sup>), available as Epzicom<sup>®</sup> or (zidovudine<sup>5</sup> + lamivudine<sup>2</sup>), available as Combivir<sup>®</sup>]

or

Nevirapine<sup>7</sup> + [(zidovudine<sup>5</sup> + lamivudine<sup>2</sup>), available as Combivir<sup>®</sup>]

**PI-based Regimens (alphabetical):**

Atazanavir/r<sup>3</sup> + [(abacavir<sup>6</sup> + lamivudine<sup>2</sup>), available as Epzicom<sup>®</sup> or (zidovudine<sup>5</sup> + lamivudine<sup>2</sup>), available as Combivir<sup>®</sup>]

or

Fosamprenavir/r once or twice daily + either [(abacavir<sup>6</sup> + lamivudine<sup>2</sup>), available as Epzicom<sup>®</sup> or (zidovudine<sup>5</sup> + lamivudine<sup>2</sup>), available as Combivir<sup>®</sup>] or tenofovir/emtricitabine<sup>2</sup>

or

Lopinavir/r<sup>4</sup> once or twice daily + either [(abacavir<sup>6</sup> + lamivudine<sup>2</sup>), available as Epzicom<sup>®</sup> or (zidovudine<sup>5</sup> + lamivudine<sup>2</sup>), available as Combivir<sup>®</sup>] or tenofovir/emtricitabine<sup>2</sup>

or

Saquinavir (Invirase<sup>®</sup>)/r + tenofovir/emtricitabine<sup>2</sup>

*Table continued in next column*

### ANTIRETROVIRAL REGIMENS FOR TREATMENT-NAÏVE PATIENTS

(Continued)

**ACCEPTABLE REGIMENS** (May be selected for some patients, but are less satisfactory than preferred or alternative regimens)

**NNRTI-based regimen:**

Efavirenz + Didanosine + [lamivudine or emtricitabine]

**PI-based Regimen:**

Atazanavir<sup>3</sup> + [(abacavir<sup>6</sup> + lamivudine<sup>2</sup>), available as Epzicom<sup>®</sup> or (zidovudine<sup>5</sup> + lamivudine<sup>2</sup>), available as Combivir<sup>®</sup>]

**Footnotes:**

1. Efavirenz should not be used during pregnancy or in women with pregnancy potential.
2. Lamivudine may be substituted for emtricitabine and vice versa, decision usually based upon availability of co-formulations.
3. Atazanavir/r should not be used in patients requiring > 20 mg daily of omeprazole [or equivalent dose of other proton pump inhibitors (PPI)]; do not use unboosted atazanavir in patients requiring a PPI or receiving concomitant tenofovir; caution with other acid-reducing agents (See Table 14a of DHHS Guidelines for dosing information).
4. Once daily lopinavir/ritonavir not recommended in pregnant women. See Perinatal Guidelines for detailed recommendations on the use of antiretroviral agents in pregnancy. [www.aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf](http://www.aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf)
5. Zidovudine available in generic formulation.
6. Abacavir should not be used in patients who test (+) for HLA-B\*5701. Use with caution in patients with high CV disease risk and with pre-treatment viral load > 100,000 copies/mL.
7. Nevirapine should not be used in patients with moderate-severe hepatic impairment or in women or men with pre-ARV CD4 > 250 or > 400 cells/mm<sup>3</sup>, respectively.
8. Didanosine EC available in generic formulation.

- The Guidelines also list regimens that “May be Acceptable” and Regimens “To be Used with Caution”
  - Although the CCR5-inhibitor maraviroc (Selzentry<sup>®</sup>) was recently FDA-approved for treatment-naïve patients ([updated label available online](#)), a maraviroc-based regimen (in combination with lamivudine/zidovudine) is listed as “May Be Acceptable” in the updated Guidelines
  - See Table 5b of the Guidelines for a full list of regimens in these categories

**References**

1. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. December 1, 2009. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. (Accessed December 1, 2009).

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