

## What's New in the Guidelines? (Last updated March 27, 2012; last reviewed March 27, 2012)

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Revisions to the October 14, 2011, version of the guidelines include both new sections and key updates to existing sections. The additions and updates, which are highlighted throughout the guidelines, are summarized below.

### New Sections

The following two new sections have been added to the guidelines.

#### *HIV and the Older Patient*

Effective antiretroviral therapy (ART) has led to greater longevity in HIV-infected individuals resulting in an increasing number of older individuals living with HIV infection. Compared with younger HIV-infected patients, older patients may have more comorbidities, which can complicate treatments of HIV and other diseases. This section focuses on HIV diagnosis and treatment considerations in the older HIV-infected patient.

#### *Antiretroviral Drug Cost Table (Appendix C)*

This new table lists the monthly average wholesale price (AWP) for U.S. Food and Drug Administration (FDA)-approved brand and generic antiretroviral (ARV) drugs, including fixed-dose combination products. (The AWP listed for an ARV may not represent the pharmacy acquisition price or the price paid by consumers for that drug.)

### Key Updates to Existing Sections

Following are key updates to existing sections of the guidelines.

#### *Initiating Antiretroviral Therapy in Treatment-Naive Patients*

The Panel updated its recommendations on initiation of ART in treatment-naive patients. The changes are primarily based on increasing evidence showing the harmful impact of ongoing HIV replication on AIDS and non-AIDS disease progression. In addition, the updated recommendations reflect emerging data showing the benefit of effective ART in preventing secondary transmission of HIV. The updated section includes more in-depth discussion on the rationale for these recommendations and on the risks and benefits of long-term ART.

The Panel's recommendations are listed below.

- ART is recommended for all HIV-infected individuals. The strength of this recommendation<sup>a</sup> varies on the basis of pretreatment CD4 cell count:
  - CD4 count <350 cells/mm<sup>3</sup> (**AI**)
  - CD4 count 350 to 500 cells/mm<sup>3</sup> (**AII**)
  - CD4 count >500 cells/mm<sup>3</sup> (**BIII**)
- Regardless of CD4 count, initiation of ART is strongly recommended for individuals with the following conditions:
  - Pregnancy (**AI**) (see [perinatal guidelines](#) for more detailed discussion)
  - History of an AIDS-defining illness (**AI**)
  - HIV-associated nephropathy (HIVAN) (**AII**)
  - HIV/hepatitis B virus (HBV) coinfection (**AII**)

- Effective ART also has been shown to prevent transmission of HIV from an infected individual to a sexual partner. Therefore, ART should be offered to patients who are at risk of transmitting HIV to sexual partners (**AI** [heterosexuals] or **AIII** [other transmission risk groups]).
- Patients starting ART should be willing and able to commit to treatment and should understand the benefits and risks of therapy and the importance of adherence (**AIII**). Patients may choose to postpone therapy, and providers, on a case-by-case basis, may elect to defer therapy on the basis of clinical and/or psychosocial factors.

### **HIV-Infected Women**

This revised section includes an expanded discussion on the use of hormonal contraception in HIV-infected women. The discussion focuses on drug-drug interactions between combined oral contraceptives and ARV drugs as well as on recent data showing a possible association between hormonal contraceptive use and acquisition or transmission of HIV.

### **HIV/Hepatitis C Coinfection**

Updates to this section focus on the newly approved HCV NS3/4A protease inhibitors (PIs) boceprevir and telaprevir, the known interactions between these drugs and ART, and interim results from current ongoing research in HIV/HCV coinfecting patients. The updated section includes preliminary recommendations on coadministration of the HCV NS3/4A drugs and ART.

### **Mycobacterium tuberculosis Disease with HIV Coinfection**

This update provides recommendations for timing of initiation of ART in HIV-infected patients who have been diagnosed with tuberculosis (TB) and are not receiving ART. The recommendations are based on results from randomized controlled trials showing survival benefits (1) when ART was initiated during rather than after TB treatment and (2) when ART was started within 2 weeks of TB treatment in patients with pretreatment CD4 count <50 cells/mm<sup>3</sup>. The updated section provides more in-depth discussions on the evidence and rationale supporting the recommendations.

The Panel's recommendations are as follows:

- For patients with CD4 counts <50 cells/mm<sup>3</sup>, ART should be initiated within 2 weeks of starting TB treatment (**AI**).
- For patients with CD4 counts ≥50 cells/mm<sup>3</sup> with clinical disease of major severity as indicated by clinical evaluation (including low Karnofsky score, low body mass index [BMI], low hemoglobin, low albumin, organ system dysfunction, or extent of disease), the Panel recommends initiation of ART within 2 to 4 weeks of starting TB treatment (**BI** for CD4 count 50–200 cells/mm<sup>3</sup> and **BIII** for CD4 count >200 cells/mm<sup>3</sup>).
- For other patients with CD4 counts ≥50 cells/mm<sup>3</sup>, ART can be delayed beyond 2 to 4 weeks but should be initiated by 8 to 12 weeks of TB therapy (**AI** for CD4 count 50–500 cells/mm<sup>3</sup>; **BIII** for CD4 count >500 cells/mm<sup>3</sup>).

### **Drug Interaction Tables (Tables 14-16b)**

These tables are updated with recent data on pharmacokinetic (PK) interactions between ARV drugs and other drugs commonly prescribed for HIV-infected patients and the Panel's recommendations on coadministration of these drugs. The key updates include:

- Change in recommendation on dosing of rifabutin with HIV PIs

- New recommendation to not use HIV PIs and non-nucleoside reverse transcriptase inhibitors (NNRTIs) with rifapentine
- Addition of information on interactions of boceprevir and telaprevir with different ARV drugs and related recommendations
- Update of interactions between different ritonavir-boosted PI and HMG-CoA reductase inhibitors.

### **Prevention of Secondary HIV Transmission**

This section is updated to discuss the role of effective ART in preventing HIV transmission. The updated section also indicates evidence-based interventions available to assist providers with HIV risk behavior identification and counseling.

#### **Additional Updates**

Minor revisions have also been made to the following sections:

- [Treatment Goals](#)
- [What to Start: Initial Combination Regimens for the Antiretroviral-Naive Patient](#) (new information regarding adverse effects of raltegravir)
- [HIV and Illicit Drug Users](#) (new drug interaction added to Table 11 included in the section)
- [Adherence to Antiretroviral Therapy](#)
- [Adverse Effects of Antiretroviral Agents](#) (and accompanying Table 13)
- [Drug Characteristics Tables](#) (Appendix B)

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<sup>a</sup> **Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = data from randomized controlled trials; II = data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = expert opinion