12-Dose Regimen for Treatment of Latent TB Infection (LTBI)
January 2012

On December 8, 2011, the U.S. Centers for Disease Control and Prevention (CDC), issued recommendations for an additional option for the treatment of latent TB infection (LTBI). CDC materials regarding this regimen is available at Recommendations for Use of isoniazid-Rifapentine Regimen with Direct Observation to Treat Latent Mycobacterium Tuberculosis Infection

This new regimen for the treatment of latent TB infection, called **the 12-dose regimen**, reduces treatment from 270 daily doses over 9 months to 12 once-weekly doses given over 3 months.

TB Treatment and Prescription Services
The Iowa TB Control Program provides medication for the treatment of all LTBI and suspected/confirmed cases of TB disease at no cost for individuals residing within the state of Iowa. See TB medications to order. However, the Program **is not** able to offer the 12-dose regimen due to the current cost. At present, the cost of this regimen is greater than ten times the cost of the standard regimen (270 daily doses of INH) used to treat LTBI. Both regimens are **equally effective** in treating LTBI. As such, clinicians or patients wishing to use the 12-dose regimen will need to obtain the medication thru private pay sources. The Program will periodically re-evaluate the feasibility of supplying this regimen

Clinicians wishing to treat patients with the 12-dose regimen are strongly encouraged to follow all published guidelines from CDC including the use of directly observed therapy (DOT), clinical monitoring for adverse reactions and patient selection for recommended and contraindicated patients. **Further, the Program request clinicians issuing the 12-dose regimen thru private pay sources notify the TB Control Program of the treatment decision.** This will allow the Program to monitor the use of the different treatment options, evaluate treatment compliance and conduct disease surveillance activities.

Key points of the 12-dose recommendation include:

- The 12-dose regimen does not replace other recommended latent TB infection treatment regimens; the 12-dose regimen is another effective regimen.
- The 12-dose treatment guideline also does not replace the current latent TB infection treatment guidelines (http://www.cdc.gov/MMWR/PDF/rr/rr4906.pdf); it is a supplement guideline.

Patients for whom the 12-dose regimen is recommended:

- The 12-dose regimen is recommended as an **equal option** to previous regimens for treating latent TB infection in otherwise healthy people, 12 years of age and older, who were recently in contact with infectious TB or who had tuberculin skin test conversions or positive blood test for TB infection.
    - HIV-infected people who are otherwise healthy and not taking anti-retroviral medicines are included in this category.
- The 12-dose regimen can be considered for other groups when it offers practical advantages, such as completion within a limited timeframe.

Patients for whom the 12-dose regimen may be considered:

- The preferred regimen for children aged 2 to 11 years old is 9 months of daily isoniazid. Use of the 12-dose regimen should be considered on a case by case basis when both **1)** the circumstances make the completion of 9 months of INH unlikely and **2)** the likelihood or the hazard of TB is great (e.g., recent TB infection in preschool-aged children).

The 12-dose regimen is NOT recommended for:

- Children younger than 2 years of age,
- People with HIV/AIDS who are taking anti-retroviral therapy,
- Pregnant women or women who expect to become pregnant during treatment, and
- People who are presumed to have been infected with isoniazid-resistant or rifampin-resistant *M. tuberculosis*.

Additional considerations:

- DOT is strongly recommended for the 12-dose regimen. Additional studies on self-administration of the 12-dose regimen are underway.
  - DOT workers should be trained on how to educate patients about adverse effects and how to inquire about adverse effects.
    - Patients using the 12-dose regimen should undergo monthly clinical monitoring, including inquiries about side effects and a physical assessment for signs of adverse effects.
    - While the 12-dose regimen was well tolerated in the three reported treatment trials, severe adverse effects (defined as effects requiring hospital admission or fatalities) should be reported to FDA MedWatch and local and state health departments immediately for inclusion in CDC's latent TB infection treatment adverse effects surveillance system.