Active tuberculosis (TB) develops in 5-10% of persons who become infected with TB. Conditions that impair immunity, such as HIV infection or diabetes, increase the likelihood of latent TB infection (LTBI) progressing to active TB disease. Preventing active TB with treatment is a cornerstone of the U.S. strategy for TB elimination. The combination regimen of Isoniazid (INH) and Rifapentine (RPT), referred to as 3HP and given as 12 weekly DOT doses, is recommended as an equal alternative to 9 months of daily INH for treating TB infection.

**Intended population include individuals diagnosed with LTBI who are:**
- 12 years of age or older
- Not pregnant and do not intend to become pregnant in the next four months
- Available for weekly DOT
- Not receiving antiretroviral treatment for HIV infection

**CDC Recommendations:**
- Educate your patient to seek medical attention upon the first symptom of a possible adverse event.
- Clinical assessment upon the first sign or symptom of a possible adverse event.
- Conduct monthly interview and brief physical examination to finding unnoticed adverse events.
- Baseline hepatic chemistry blood tests, such as alanine aminotransferase (ALT) for patients with specific conditions:
  - HIV
  - Liver disorders
  - Postpartum (< 3 months after delivery)
  - Regular alcohol usage
- Consider baseline hepatic chemistry blood test for older patients, especially for those taking medications for chronic conditions.
- Blood tests at subsequent clinical encounters for patients whose baseline testing is abnormal and for others at risk for liver disease.
- Discontinue INH-RPT if serum aminotransferase concentration is ≥ 5 times the upper limit of normal, in the absence of symptoms, or ≥ 3 times the upper limit of normal in the presence of symptoms.
- Be vigilant for drug hypersensitivity reactions, particularly hypotension or thrombocytopenia.
  - In severe conditions (e.g., hypotension requiring intravenous fluids) you should discontinue INH-RPT.
  - For mild to moderate conditions (e.g., dizziness treated with rest or oral fluids) use conservative management of constitutional symptoms, clinical and laboratory monitoring, and provide the option for continuing treatment under observation.
Other Considerations:

- Women on any form of hormonal contraceptive should be:
  - Advised regarding drug interactions with Rifapentine lowering the effectiveness of hormonal methods and the possibility of contraceptive failure.
  - Advised to add or switch to a barrier or other non-hormonal method during the 3HP treatment regimen.

- Provide client education about LTBI
  - Education should be provided in the client's primary language and at an educational level appropriate to the client.
  - Assure client has an opportunity to ask questions concerning treatment regimen.
  - The following resources can be used when providing education for the client with TB infection:
    ii. [http://www.cdc.gov/tb/publications/pamphlets/12doseltbitreatmentbrochure8.5x11.pdf](http://www.cdc.gov/tb/publications/pamphlets/12doseltbitreatmentbrochure8.5x11.pdf)
    iii. [https://apps.state.or.us/cf1/DHSforms/Forms/Served/le8363.pdf](https://apps.state.or.us/cf1/DHSforms/Forms/Served/le8363.pdf)

- Use a worksheet or system to help keep track of doses, symptom monitoring, patient education, and bloodwork. An example of a weekly monitoring worksheet is provided below and should be adapted for each individual patient. If you would like a copy of the editable Word document please email mcguirkh@michigan.gov.

**ALT**, alanine aminotransferase **CDC**, Centers for Disease Control and Prevention; **DOT**, directly observed therapy; **HIV**, human immunodeficiency virus; **INH**, Isoniazid; **LTBI**, latent tuberculosis infection; **RPT**, Rifapentine; **TB**, tuberculosis

<table>
<thead>
<tr>
<th>Date:</th>
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<tbody>
<tr>
<td>TB symptoms (persistent cough, weight loss, fever, night sweats, etc.):</td>
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<table>
<thead>
<tr>
<th>ADVERSE DRUG EVENTS</th>
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<tbody>
<tr>
<td>Loss of appetite (INH/RPT)</td>
</tr>
<tr>
<td>RUQ abdominal discomfort (INH/RPT)</td>
</tr>
<tr>
<td>Unusual/Excessive fatigue (INH/RPT)</td>
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<tr>
<td>Nausea/Vomiting (INH/RPT)</td>
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<tr>
<td>Unexplained fever ≥ 3 days (INH/RPT)</td>
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<tr>
<td>Urine color change (dark) (INH/RPT)</td>
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<tr>
<td>Stool color change (light) (INH/RPT)</td>
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<tr>
<td>Jaundice (yellow skin/eyes) (INH/RPT)</td>
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<tr>
<td>Skin rashes/itching (INH/RPT)</td>
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<tr>
<td>Numbness/tingling in arms/legs (INH)</td>
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<tr>
<td>Flu-like symptoms (RPT)</td>
</tr>
<tr>
<td>Unusual bleeding/bruising (RPT)</td>
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<tr>
<td>Change in urine output (RPT)</td>
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</tbody>
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<table>
<thead>
<tr>
<th>EDUCATION</th>
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</thead>
<tbody>
<tr>
<td>Stop medication and notify nurse if adverse drug events occur</td>
</tr>
<tr>
<td>Signs/symptoms of TB disease</td>
</tr>
<tr>
<td>Avoiding alcohol use and exposure to other hepatotoxins</td>
</tr>
<tr>
<td>Orange discoloration of body fluids</td>
</tr>
<tr>
<td>Date of LMP: Effect on hormonal contraceptives (RPT)</td>
</tr>
<tr>
<td>Adherence; treatment completion</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MEDICATION DOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>INH _____ mg</td>
</tr>
<tr>
<td>RPT _____ mg</td>
</tr>
<tr>
<td>DOT provider’s initials</td>
</tr>
<tr>
<td>Client’s initials</td>
</tr>
</tbody>
</table>

**Complete When Closing Case**

Total # doses ingested: ____________  Total # weeks on therapy: ____________  Completed therapy: Yes  No

Note: Completion of treatment is defined as: eleven (11) or twelve (12) doses must be given within 16 weeks. Each dose must be separated by > 72 hours.