Texas Department of State Health Services

Tuberculosis (TB) Medication Usage Criteria During Drug Shortages

RIFABUTIN

Rifabutin is in short supply and may only be provided for patients who meet criteria in this document until further notice.

Rifabutin may ONLY be used for these priority patients:

- Patients with known or suspected TB disease in whom there are high-risk drug interactions with rifampin as specified below (see Section 1, A).
- Patients with known or suspected TB disease who have a documented failure to tolerate rifampin.
- Certain patients on treatment for latent TB infection (LTBI) or window prophylaxis as detailed on page 2.

When medical consultation is required, contact a DSHS-recognized TB medical consultant: dshs.state.tx.us/idcu/disease/tb/consultants/

Section 1: Rifabutin Criteria for Known/Suspected TB Disease

A. For new or existing patients in whom rifampin is contraindicated (due to high-risk drug interactions): Rifabutin may be used.

High-risk drug interactions are:

- Antiretrovirals (ARVs) for HIV (refer to Table 1)
- Anti-rejection medications for transplant patients (not limited to cyclosporine, tacrolimus)
- Methadone
- **By consultation only:** Other medications where the provider is unsure if rifampin is contraindicated. Refer to the <u>DSHS Standing Delegation Orders</u> (SDOs), page 42, Table 2 and page 46, Table 4 footnotes on rifampin when deciding on rifabutin or rifampin.
- **B.** For *new* patients needing a liver friendly regimen: Rifampin is usually tolerated.
 - Rifampin should first be used (e.g., a regimen with rifampin/fluoroquinolone/ethambutol).
 - For patients who failed the initial rifampin challenge, document results and proceed with rifabutin. No consultation required.

C. For *existing* patients initially on rifampin but developed a <u>documented</u> adverse reaction to rifampin:

• Continue rifabutin. No consultation required.

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Section 2: Rifabutin Criteria for Latent TB Infection (and Window Prophylaxis)

- **A. For new patients:** Do NOT start on rifabutin.
 - If unable to use rifampin or rifapentine, use the 6-month isoniazid regimen.
 - If isoniazid is not an option, seek medical consultation.

B. For existing patients on rifabutin, use one of the following options:

- Rifampin should be challenged unless there is an **absolute** contraindication. If successfully challenged, complete therapy with rifampin with no change in completion date.
- If patient cannot transition to rifampin:
 - If less than 2 months of treatment remain, continue rifabutin and complete 90 days/18 weeks (if directly observed therapy [DOT]) or 120 doses/4 months (if self-administered).
 - If greater than 2 months of treatment remain, transition to isoniazid, and complete a total of 6 months (e.g., if patient took 1 month of rifabutin, they would need 5 months of isoniazid for a total of 6 months of treatment).
 - If isoniazid is not an option, seek consultation.

Follow these steps when ordering rifabutin:

- 1. Verify that patient meets ordering criteria and if needed, obtain consultation.
- 2. Ensure the patient is entered in NEDSS and has an investigation ID.
- 3. Order rifabutin in PIOS.
 - In the comments section, include the NEDSS investigation ID.
- 4. Once a PIOS order number is generated, complete *TB Medication Request Form*.
 - All applicable fields must be complete, including noting the PIOS order number and NEDSS investigation ID.
- 5. Upload the completed *TB Medication Request Form* (and consult, if required) to the supplemental information tab in the NEDSS investigation.
 - The DSHS Pharmacy Unit will *automatically* forward any rifabutin order received in PIOS directly to the TB Unit Clinical Care Team (CCT).
 - The CCT will verify the order with the *TB Medication Request Form* and approve or deny. NOTE: CCT will <u>only</u> be able to verify request if the NEDSS ID is noted in PIOS and form/consult is uploaded in NEDSS. Submitters will be notified if they are denied. Orders will be filled if approved.

No generic clinic stock orders are allowed during this shortage.

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Table 1: Rifampin and Known Anti-Retroviral (ARV) Contraindications

Rifampin is contraindicated in patients with HIV who are receiving one or more of the following anti-retroviral (ARV) medications:

- 1. PI (all PIs contraindicated with rifampin or rifapentine): **atazanavir, darunavir, lopinavir, nelfinavir, saquinavir, tipranavir**. *NOTE: Though compatible with rifabutin, may require lower doses of rifabutin.*
- 2. NNRTI: **doravirine, etravirine, nevirapine, rilpivirine**. *NOTE: Efavirenz is an NNRTI that can decrease drug levels of rifabutin but can be used with weekly rifapentine, and dose adjusted for use with rifampin.*
- 3. NRTI: **zidovudine, tenofovir alafenamide (TAF).** *NOTE: TAF is incompatible with ALL rifamycins. All other NRTIs can be used with rifampin.*
- 4. INSTI: **dolutegravir**. NOTE: raltegravir is compatible with weekly rifapentine; bictegravir is incompatible with ALL rifamycins.

For more information, refer to: Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. (2021)

<u>clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/tuberculosishiv-coinfection</u>