

Texas Department of State Health Services  
**Notification of Tuberculosis Medication Availability**

The availability of first-line tuberculosis (TB) medications is in fluctuation leading to drug shortages. Reasons include gaps in the supply chain, shortages of active pharmaceutical ingredients (API), and manufacturers' decisions to stop producing drugs. Some shortages are listed on the Food and Drug Administration (FDA) website while others involve delays in procuring medications.

This document outlines the current actions local and regional TB programs must adhere to when ordering TB medications during drug shortages, until otherwise directed by the DSHS Tuberculosis and Hansen's Disease Unit.

**Medication details effective October 3, 2022:**

**General Updates:**

- **Rifampin** is currently available for patients on treatment for TB disease.
- **Rifabutin** is in critical shortage and is available for a limited population.
- **Rifapentine** is in short supply. Please follow guidelines in Table 1 when considering treatment for TB infection and window prophylaxis.
- Reserve the use of rifamycins for patients with active TB.
- Updated options for TB infection, including window prophylaxis, are outlined in Table 1.
- Continue to order in 30-day increments.
- Bulk orders may be placed per usual.

Drug: **Rifabutin**

Availability Status: **Critical shortage, limited availability**

Action:

- Do not start any new patients on rifabutin *routinely*.
- Rifabutin is allowed ONLY for patients who:
  - are taking protease inhibitors (PIs) and/or nonnucleoside reverse transcriptase inhibitors (NNRTIs) where there is a drug/drug interaction;
  - are taking tacrolimus;
  - are transplant recipients ([medical consultation](#) is required prior to treatment initiation);
  - are taking methadone;
  - have a documented sensitivity/intolerance to rifampin.
- Review any drug/drug interactions prior to using rifamycins. Suggested resources include [https://www.drugs.com/drug\\_interactions.html](https://www.drugs.com/drug_interactions.html) and [Tuberculosis Medication Drug and Food Interactions](#), published by Heartland National TB Center.

*NOTE: As rifabutin is in a critical shortage, [medical consultation](#) is required for any other use not listed above.*

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**Drug: Rifampin**

**Availability Status: Available**

**Action:**

- Transition all patients currently taking *rifabutin* back to *rifampin* (including TB infection/window prophylaxis) unless rifampin is contraindicated.
  - Exhaust the patient’s current rifabutin supply and then switch to rifampin to complete therapy.
  - Obtain a new physician order and ensure the patient has signed a new [medication consent form](#) when changes occur.
  - Refer to the [DSHS Standing Delegation Orders](#) (SDOs) for rifampin dosing.
- Start all *new* patients needing treatment for TB disease on rifampin, unless contraindicated.
- For *new* patients needing treatment for TB infection refer to Table 1.

*Note: Caution should be used in patients taking Coumadin who are switched from rifabutin to rifampin. Coordination with primary care providers should occur, and providers should be advised to monitor international normalized ratio (INR) levels closely and ensure therapeutic level of anti-coagulation.*

**Options for Treatment of TB Infection**

While short-course options for TB infection are preferred, drug shortages require a temporary shift in usual practice by all Texas TB programs who may need to modify usual case management practices to support adherence. This includes considering direct observation of therapy (DOT) for longer regimens, incorporating video-enabled DOT (VDOT) when it would otherwise be self-administered, or enhancing care through periodic check-ins between monthly appointments (enhanced self-administration [ESAT]).

***The TB Unit has provided options for TB infection regimens with the understanding that isoniazid (INH) is preferred as it is the most readily available drug.*** Rifampin may be considered if there is a true contraindication to INH. The INH/Rifapentine 3-month regimen (3HP) may also be considered for select patients who will not adhere to a longer INH regimen. Refer to Table 1 below for options.

**Table 1.** Treatment Options\* for New Patients: TB Infection, Window Prophylaxis

<b>Option 1 - Preferred</b>	<b>Option 2</b>	<b>Option 3</b>
<b>6 or 9 Months INH (6H or 9H)</b>	<b>4 Months Rifampin (4R)</b>	<b>3 Months Once Weekly INH/RPT (3HP)</b>
<ul style="list-style-type: none"> <li>• Use this regimen option for the following patients:               <ul style="list-style-type: none"> <li>○ Those with no drug/drug interactions or contraindications;</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Reserved ONLY for patients in whom INH is contraindicated.</li> </ul>	<ul style="list-style-type: none"> <li>• Rifapentine availability is limited. Consider this regimen if Option 1 is not possible.</li> </ul>

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<ul style="list-style-type: none"> <li>○ those with no risk factors for hepatotoxicity;</li> <li>○ those <i>not</i> exposed to a case of TB that is resistant to INH.</li> <li>● <b>As this is a regimen with the longest duration, it is important for clinics to support patient adherence.</b> <ul style="list-style-type: none"> <li>○ DOT is <u>highly recommended</u> to ensure completion of treatment (either in-person or by VDOT).</li> <li>○ Twice weekly DOT/VDOT is an option at the discretion of the licensed healthcare provider.</li> </ul> </li> </ul>		

\*Refer to the [DSHS SDOs, Attachment 7: Medications](#)

**Additional Information**

Patient education:

- Communicating drug shortages or switching patients from one drug to another may cause some concern in patients.
- Consider sharing information about drug shortages in general, as explained on the Food and Drug Administration (FDA) website: <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>
- Patients may be directed to the DSHS TB Unit website to see this information <https://www.dshs.texas.gov/disease/tb/news.shtm>.
- Assuring patients that the medications used will support their treatment plan may help alleviate any concern about changes in the regimen.

Medication Orders:

- Please work with the licensed healthcare provider to switch all patients to rifampin unless contraindicated *as soon as possible*.
- The DSHS Standing Delegation Orders provide direction on verbal orders; refer to [page 9, #12](#), for details.