

WV Tuberculosis Elimination Program Standards Of Care Protocol for Latent Tuberculosis Infections (LTBI)

WV Tuberculosis Elimination Program's (WV TBEP) Mission

The mission of the WV TBEP is to eliminate tuberculosis in West Virginia. This will be accomplished by assuring compliance with effective TB strategies, by all WV TBEP clinics providing consistent quality standard of care, and by coordinating the efforts of private providers with public health when providing care to TB patients.

Standards of Care for all WV TBEP Clinics for LTBI

1. Once the LHD is first made aware of the case they need to obtain all the needed records on the case from the reporter. This includes:
 - a. Demographic information.
 - b. Any radiographical procedure reports if they were done.
 - c. All lab results that were done pertaining to the diagnosis.
 - d. Find out the reason the case was initial tested for TB.
2. Contact the case and inform them of our role in their care for LTBI and complete a TB-104 Risk Assessment Form. Be sure to fill out the form completely and fax the form to WV TBEP at (304) 558-1825. If there are **NO** contraindications on doing a repeat test one should be offered to all LTBI referrals. **These contraindications are:**
 - a. If the case has ever had an exposure to an active case of TB, they will need to be seen in clinic.
 - b. If the case has symptoms of active TB contact WV TBEP immediately.
 - c. If the case is on a medication or getting ready to start medication that weakens their immune system or increases their risk of infection they will need to be seen in clinic.
 - d. If the case has a history of positive TB screening tests they will need to be seen in clinic.
 - e. If the case is HIV positive, they will need to be seen in clinic.
 - f. If the case is under 2 years of age they will need to be seen in clinic.

(IGRA's are the preferred test for WV TBEP and should be the first choice when doing TB testing unless it is contraindicated. A PPD should never be done on a case that has a history of BCG vaccine or anyone who has been treated with BCG for bladder cancer.)

3. If an IGRA or additional TB screening test is done:
 - a. If the IGRA or additional TB screening test is positive the case will need to be seen in clinic.
 - b. If the IGRA or additional TB screening test is negative the case does not need to be seen in clinic and no further action is needed. Document your finding in WVEDSS.

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- i. Provide all the needed documentation to the individual for their records.
 4. For every case that needs to be seen in clinic a chest xray needs to be obtained that is no older than 3 months. If one has not been done or is outdated contact WV TBEP to schedule one (If WV TBEP is unable to schedule an xray an order will be provided along with a send out letter).
 - a. Contact WV TBEP with any abnormal chest x-ray's consistent with active TB. Sputum will need to be obtained to rule out active TB.
 - i. If sputa are needed, 3 consecutive days sputum needs to be collected and sent to Office of Laboratory Services (OLS) for Acid Fast Bacilli (AFB) smear and culture testing, if you have any questions regarding lab submission please contact OLS. You will need to provide the case with 3-4 sputum containers with instruction on how to collect them and what to do with the specimen once it is obtained. If the case cannot produce sputum contact WV TBEP for further instructions.
 - ii. There are standing orders for collecting sputum, the order can be found on our website under Standing Orders for Sputum Collection.
 - iii. Please refer to Health Care Worker Sputum Collection Instructions for instructions on how to properly collect, store and ship the sputum.
 - iv. Please give the case the Patient Sputum Collection Instructions form on how to properly collect and store the specimen until it is obtained by you.
 5. For every case that needs to be seen in clinic a TB-80 Diagnostic Clinic Form needs to be completed and faxed to WV TBEP with a copy of any radiographic results, TB testing results and a copy of any medication the case is currently taking. This form is what will prompt a diagnostic clinic being scheduled. **NO CLINIC WILL BE SCHEDULED UNTIL THE TB-80 FORM IS RECEIVED.** This form does not need to be sent if the person does not need scheduled for diagnostic clinic. The form is to be filled out completely by the nurse. **THE CASE SHOULD NOT FILL OUT THE TB-80.**
 - a. For counties managed by the WV TBEP clinician once WV TBEP receives the form and all the required documentation someone will contact you with dates and times for clinic.
 - b. If it is a county that is managed by a contracted clinician this form and all the required documentation still needs to be faxed to WV TBEP when a case is scheduled for diagnostic clinic so that we can track the progress of the case. Please make sure that you always add the date the case was seen in clinic on the form.
 6. WV's mission is to eliminate TB. In 2011, CDC recommended a short-course combination regimen of once-weekly isoniazid and rifapentine for 12 weeks (3HP) by

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Direct Observed Prophylaxis Therapy DOPT for treatment of LTBI. In 2018 CDC updated their recommendations for use of 3HP for treatment of LTBI in adults and now recommend use of 3HP in children with LTBI aged 2–17 years, in persons with LTBI who have HIV infection, including AIDS, and are taking antiretroviral medications with acceptable drug-drug interactions with rifampine. Based on CDC’s evidence on effectiveness, safety, and treatment completion rates 3HP is WV TBEP’s preferred regimen for all cases seen in clinic that meet the requirements for this treatment. If 3HP is contraindicated WV TBEP recommends a shorter course of treatment to be utilized to increase the chance of treatment completion, such as Rifampin 4months regimen. Isoniazid 6-9 months regimens should only be used as a last resort due to the duration and decreased treatment completion rates.

7. During the clinic the case will get to talk to the clinician. WV TBEP has developed an order set that is to be used during clinic by the clinician.
 - a. For the counties with contracted clinician the order set is to be filled out and faxed to WV TBEP after each clinic.
8. The following is a list of things that need to be done for all LTBI cases seen in clinic that will be starting medication:
 - a. Provide HIV counseling and testing if not already done. If it has been done find out where and obtain a copy of the results.
 - b. Provide Hepatitis C and Hepatitis B testing if not already done. If it has been done find out where and obtain a copy of the results.
 - c. Obtain baseline labs. These include the following:
 - i. CBC- this is only done at the initiation of treatment unless ordered more frequently by the clinician.
 - ii. CMP- this is only done at the initiation of treatment unless ordered more frequently by the clinician.
 - iii. And any other labs the clinician will need to properly care for the case. For contracted clinicians please contact WV TBEP to ensure labs are covered by WV TBEP before ordering.
 - d. Obtain the initial weight of the case.
 - e. LTBI cases will only need to be seen once in clinic by the clinician unless:
 - i. Ordered to returned by a clinician.
 - ii. If the case requests to be evaluated by a clinician.
 - iii. If problems occur during treatment.
 - f. If the clinician recommends LTBI treatment for a case, please refer to the [Treatment Protocol](#) for information on how DOPT is to be done for the ordered regimen, if it is required. The Treatment Protocol will also explain by who it is to

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be done and why it is to be done. There are two different forms you will need to use for DOPT. These two forms are:

- i. TB-107 DOT Treatment Record- this form is used to document every dose given by DOPT and to keep a recorded total of how many doses the case receives. This record will be faxed to WV TBEP at the end of treatment.
 - ii. TB-150 Workers Log- this form is for billing purposes. WV TBEP is able to provide some reimbursement to the Local Health Departments for the time the nurse spends conducting DOPT for TB cases. Please refer to the WV TBEP DOPT Reimbursement Breakdown for more details.
- g. Educate the case on TB medications, hepatotoxicity and the side effects that they can cause. Provide contact information for the health department so that they know how to contact someone with any questions or concerns about treatment. According to which regimen the clinician orders you will need to do the following:
- i. Read and review the Medication Fact Sheet for each medication the case is on and provide them with a copy.
 - ii. Give the case a copy and review with them the Treatment Plan for LTBI prior to consents being signed.
 - iii. Have the case read and sign a TB-106 Consent for Treatment Form.
- h. Explain to them how and why DOPT is done for their regimen.
- i. If the clinician ordered 3HP please review the Hydration Protocol with the case.
- j. Explain to the case that medication administration will begin once we receive the LFT results, and they have been reviewed by the clinician.
- i. Please refer the Standing Order for Hepatotoxicity on how to interoperate the LFT's and on what to do with any abnormal results.
- k. Take this time to discuss what time is best to do the DOPT and schedule your DOPT visits.
- l. Educate the case on the need for repeat LFT testing.
9. Review the TB-110 Clinical Pathway for Managing an LTBI Case- this form is used to document when each task is done during treatment.
10. Once the LFT's have been reviewed and you have received the medication from WV TBEP you may begin the regimen.
- a. Fill out the Medication Dispensing Record Form, TB-50, for **ALL PATIENTS** who are receiving medication. It is required that the name, strength, manufacturer, lot number and expiration date of medication dispensed by the Local Health Department for each bottle of medication be documented each time medication

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- is dispensed. Once the patient has completed treatment, the forms should be sent to the WV TBEP.
- b. If DOPT was ordered administer the medication by DOPT and be sure to document the administration on the TB-107 DOT Treatment Record.
11. Regimen specific administration information:
 - a. 3HP will always be done by DOPT.
 - b. For all other regimen, the first dose is always done by DOPT to ensure there is not an adverse drug reaction to the medication.
 12. For all other regimen besides 3HP a monthly supply of medication can be given to the case unless the clinician orders LFT's more frequently than once a month. Give the case enough medication to last them until they must return for LFT's. **Again, be sure to fill out the Medication Dispensing Record Form, TB-50, for ALL PATIENTS.**
 13. For the rest of the treatment continue the following:
 - a. DOPT if the regimen requires it.
 - i. For 3HP this will continue until the case has completed the required 12 doses.
 - b. Assess for adverse drug reactions and hepatotoxicity and contact WV TBEP or the clinician with any findings.
 - c. Continue monitoring of LFT's and fax them to WV TBEP to be put in the case file.
 - d. Follow the schedule of the Clinical Pathway.
 14. At the completion of treatment obtain LFT's 1 week after completion of treatment.
 15. After you receive the results fax in a copy of the completed DOPT record for a dose count to be done along with the last LFT's to be reviewed by WV TBEP.
 16. Once they have been reviewed a discharge order and Completion of Treatment form will be sent to for the case.
 - a. Review the discharge orders with the case.
 - i. If it is a county that is managed by a contracted clinician fax in a copy of the discharge order and a copy of the Completion of Treatment letter to WV TBEP.
 17. The case should be instructed not to receive another TB test and why. When necessary, they should provide the completion of treatment letter and a risk assessment should be completed instead and if necessary, a chest xray should be done.
 18. Provide the case a Completion of Treatment Letter.
 19. Fax a copy of the completed Clinical Pathway and all other forms to WB TBEP.