

# Tuberculosis Care Guide

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CALIFORNIA CORRECTIONAL  
HEALTH CARE SERVICES

*Information contained in the Care Guide is not a substitute for a health care professional's clinical judgment. Evaluation and treatment should be tailored to the individual patient and the clinical circumstances. Furthermore, using this information will not guarantee a specific outcome for each patient. Refer to "Disclaimer Regarding Care Guides" for further clarification.*

<https://cchcs.ca.gov/clinical-resources/>

## Stakeholders and Reviewers

The Tuberculosis (TB) Care Guides have been revised and feedback was solicited and incorporated from the following stakeholders:

- The California Department of Public Health Tuberculosis Control Branch
- Physicians and Public Health Nurses working within California Department of Corrections and Rehabilitation Institutions
- California Correctional Health Care Services (CCHCS) Public Health, Medical Services
- CCHCS Public Health Nurse Consultants Program Review, Nursing Services

## Record of Changes

- Combined all five prior TB Care Guides into one document:
  - Tuberculosis Surveillance Care Guide, September 2018
  - Tuberculosis Contact Investigation Care Guide, April 2018
  - Tuberculosis Infection Management Care Guide, February 2018
  - Tuberculosis Disease Care Guide, April 2017
  - Tuberculosis Diagnosis and Isolation Care Guide, April 2015
- Added chest pain as a symptom for tuberculosis disease. Chest pain is included as a symptom of TB in the Centers for Disease Control and Prevention (CDC) guidance.
- Expanded the annual screening table to include all registry status. Removed the annual screening algorithm due to redundancy as all information is included in the table. Removed follow up of TB Infection (LTBI) patients not on treatment table as redundant with the annual screening table.
- Introduced TB infection for latent TB infection (LTBI).
- Added rifampin and isoniazid “3HR” regimen to the TB infection regimens as per the CDC recommendations for TB infection therapy.
- Changed the timing of nursing visits for patients on TB infection therapy to monthly for all regimens instead of weekly for the rifapentine and isoniazid “3HP” and rifampin “4R” regimens.
- Added a recommended provider visit at the end of TB infection treatment to assess overall adherence, assess any adverse reactions, address any concerns, and ensure appropriate documentation of completion.
- Replaced rifamycin drug interaction table with a referral to the UCSF Curry International TB Center’s Rifamycin drug interactions page.
- Added patients who refuse testing to the group of patients who will require more frequent monitoring. Testing refusal precludes classification for TB infection and so these patients will require monthly symptom screening for two years after entry. This is reflected in the Section I, Table 2: Annual Evaluation Requirements Based on TB status.

Questions can be addressed to CCHCS Public Health Services at [CDRCPHCSPublicHealth@cdcr.ca.gov](mailto:CDRCPHCSPublicHealth@cdcr.ca.gov)

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## Purpose and Structure

This California Correctional Health Care Services (CCHCS) Tuberculosis Care Guide is a tool to aid health care practitioners, leadership, public health and infection control nurses, and other staff in the identification, treatment, and management of tuberculosis.

Tuberculosis (TB) may cause substantial morbidity and mortality within corrections. California Department of Corrections and Rehabilitation (CDCR) and CCHCS are responsible for creating and enforcing guidelines to assess, screen, treat, and contain TB within CDCR institutions in a manner consistent with community standards. Additionally, Penal Code Sections 7570 through 7576 require that all patients receive the required annual TB surveillance, testing, education, and medically necessary treatment to prevent the spread of TB within institutions.

## Tuberculosis Background and Epidemiology

### A. Overview

TB is caused by members of the *M. tuberculosis* complex of bacteria, including *Mycobacterium tuberculosis*, *M. bovis*, *M. africanum*, *M. microtii*, *M. canetti*, *M. caprae*, *M. pinnepedii*, and *M. orygis*. Worldwide it is the 13<sup>th</sup> major cause of death and in 2020 was responsible for over 1.5 million deaths globally. Within the United States, the incidence of TB has declined since the early 1990s. Most cases of TB in the US are now identified in foreign-born persons. However, TB is a concern in corrections as outbreaks have been recorded in jails and prisons with significant morbidity.

### B. Symptoms and Clinical Course

*M. tuberculosis* complex bacteria are transmitted primarily in respiratory aerosols. Following exposure, persons may immediately clear the organism, may develop active disease (this is known as primary disease), or develop a latent infection. For individuals with latent infection (also known as latent TB infection, or LTBI), reactivation of disease may occur—i.e., infectious (active) TB disease, many years after initial infection.

Reactivation occurs in 5-10% of persons with latent disease. For persons with HIV infection, other immunocompromising conditions (including cancer and diabetes), the risk for reactivation is much higher. Reactivation risk is highest in the first two years after initial TB infection.

Patients with active disease may present with the following symptoms: prolonged cough (> 2 to 3 weeks), weight loss, fever, chills, night sweats, hemoptysis, chest pain, fatigue, and decreased appetite among other symptoms. TB disease may primarily affect the lungs but can disseminate to affect other areas of the body including meninges and bones.

### C. Transmission

*M. tuberculosis* complex bacteria are transmitted in respiratory aerosols that are expelled by a patient with active pulmonary or laryngeal TB disease when speaking, coughing, sneezing, singing, or during an aerosol generating procedure (AGP). These aerosol droplets may remain suspended in the air for several hours depending upon a variety of environmental factors including air exchange and ventilation. Infection occurs when a person inhales droplet nuclei containing *M. tuberculosis* complex bacteria. Vertical transmission resulting in congenital TB is rare but has been documented.

### D. Incubation Period

The incubation period for TB may be weeks to years following exposure and infection. Generally, tests to diagnose TB infection like an interferon gamma release assay (IGRA) or tuberculin skin test (TST) may become positive within 8 to 10 weeks following exposure. These tests are negative in early active/infectious disease and so cannot be used to rule out active TB disease.

### E. Infectious Period

Persons with TB are only infectious when they have active disease that involves their lungs or larynx. Persons with extrapulmonary TB disease may have concurrent unsuspected pulmonary or laryngeal TB disease and therefore should be ruled out for pulmonary disease. Except for co-existing laryngeal or pulmonary TB disease, extrapulmonary TB disease is rarely infectious.

## Tuberculosis Background and Epidemiology, cont'd

The infectious period prior to symptom onset varies; for the purposes of a contact investigation, the laboratory testing (e.g., respiratory sputum specimens) will help determine time frame for the investigation. Please see **Section VII Contact Investigation** for more details.

Any patient diagnosed with confirmed or suspected active infectious TB disease will be placed in respiratory isolation, see **Section IV Isolation and Movement** for more details.

### F. Prevention

Persons with suspected or confirmed active TB disease identified through entry screening, annual screening, interim screening, or a contact investigation should be rapidly isolated and treated. Following diagnosis of a patient with active TB disease, a contact investigation should be performed to identify persons who were exposed to the patient to prevent further transmission. See **Section VII Contact Investigation** and **Section VI (Active) Tuberculosis Disease Management** for more details.

Persons with TB infection should be treated to prevent reactivation disease. See **Section V Tuberculosis Infection Management (Latent Tuberculosis Infection)** for more details.

### G. Diagnosis

Patients with signs and symptoms of active TB should be evaluated by a medical provider to rule out active TB disease. This includes both symptom screening as well as diagnostic testing, including chest imaging to look for pulmonary disease.

Patients may be screened for LTBI with an IGRA or TST. Patients with a positive IGRA or TST, but who are asymptomatic and do not have findings on chest imaging (e.g., chest x-ray, or CXR), are considered to have LTBI and are non-infectious. Please note that IGRA and TST can be falsely negative in patients with (active) TB disease.

Please see **Section I Screening and Surveillance for Tuberculosis** and **Section III Diagnosis of (Active) Tuberculosis** for a more detailed discussion.

### H. Treatment

Patients with high suspicion of infectious active TB disease should be managed by a TB Care Team and treated using an appropriate multi-drug regimen.

Please see **Section VI (Active) Tuberculosis Disease Management** for more detail regarding the TB care team, medical classification chrono (MCC) requirements, discussion of medical holds, drug regimens, and special populations.

Patients with TB infection (latent TB infection, LTBI) should be treated to prevent reactivation and infectious (active) TB disease. Patients must not be treated for (latent) TB infection until (active) TB disease has been ruled out with a symptom screen and imaging, and potentially sputum culture. Discussion of (latent) TB infection treatment is found in **Section V Tuberculosis Infection Treatment (Latent Tuberculosis Infection)**.

## Section I: Screening and Surveillance for Tuberculosis

### A. Purposes of Screening and Surveillance

The purpose of surveillance is to protect CDCR incarcerated people, staff, and volunteers, from TB disease:

- Identify patients with active TB disease and ensure those patients are isolated appropriately to prevent transmission.
- Ensure patients with active TB disease are treated.
- Identify patients with LTBI.
- Encourage LTBI treatment to prevent development of active TB disease.

## Screening and Surveillance for Tuberculosis, cont'd

### B. Institution Screening Requirements

All patients are screened for (active) TB disease upon entry to the CDCR at reception centers as well as for TB infection (i.e., LTBI).

Screening for (active) TB disease is mandated at intake to the Reception Center, annually, and as per Health Care Department Operations Manual 3.8.7 Tuberculosis Surveillance Program.

IGRA and TST are not currently required on an annual basis for incarcerated people who reside continuously within CDCR. Incarcerated people who had a negative test upon entry are considered to be at low risk for newly acquired infection given the current epidemiology of TB within CCHCS/CDCR.

### C. Reception Center Screening Procedure

All patients shall be screened for symptoms of active TB on the day of arrival including:

- Prolonged cough (> 2-3 weeks)
- Hemoptysis (coughing up blood)
- Chest pain\*
- Fever
- Chills
- Night sweats
- Fatigue\*
- Unintentional weight loss
- Anorexia\* (loss of appetite)

\*Some of these symptoms in isolation are very non-specific (e.g., fatigue, anorexia, and chest pain); therefore, providers may use their discretion in determining what if any evaluation is required. These symptoms may be indicative of other medical issues (cardiac, malignancy, etc.). Please see Section III Diagnosis of (Active) Tuberculosis for a more in-depth discussion of symptoms of (active) TB disease and work up.

#### Symptomatic Patients:

All patients with symptoms or signs of TB (regardless of IGRA or TST result) shall be given a procedure mask and evaluated in the Triage and Treatment Area (TTA) for TB disease by a provider, which may include:

- IGRA or TST (if no documentation of a prior positive result)
- A chest x-ray (CXR)
- Sputum smears and cultures for Acid-Fast Bacilli (AFB)

Contact the sending institution to obtain additional available medical information.

#### Asymptomatic Patients

Patients who are negative on symptom and screen and with prior negative TB test (i.e., IGRA test or negative TST) or unknown or inadequate documentation of TB infection status shall have an IGRA (preferred) or TST performed at a Reception Center. IGRA testing is strongly preferred in persons who are non-U.S. born as they are more specific than TST.

IGRA and TST testing is not indicated if:

- Documented history of a positive IGRA test at any time in the past.
- Documented negative IGRA within the past 30 days.
- Documented TST with any reading interpreted as positive at any time in the past.
- Documented TST <5mm in past 30 days for patient with a high-risk condition or recent exposure to a person with infectious TB disease.
- Documented TST <10mm in past 30 days for patient without a high-risk condition.

A CXR should be ordered in certain asymptomatic persons including those with HIV and other immunosuppressed persons, and in persons with positive IGRA or TST results. Please see Section II Table 1 below for a discussion on indications for CXR in asymptomatic patients.

## Screening and Surveillance for Tuberculosis, cont'd

### Section I Table 1. CXR Indications for Asymptomatic Patients

IGRA or TST (mm)	High Risk condition*	CXR recommendation
IGRA positive	Not applicable	Obtain CXR to evaluate for TB disease
IGRA negative	Not applicable	No CXR
0 - ≤ 4 mm	Not Applicable	No CXR
5 - 9 mm	Yes	Obtain CXR to evaluate for TB disease
5 - 9 mm	No	No CXR
≥ 10 mm	Not Applicable	Obtain CXR to evaluate for TB disease

#### Patients with Diagnosed HIV:

Asymptomatic patients with a known HIV diagnosis shall receive a 2-view CXR within 72 hours of arrival at reception unless their records contain documentation of a normal or stable CXR within the preceding 30 days. The CXR should be read in 24 hours.

- Any patient with a diagnosis of HIV who has a CXR abnormality that cannot be documented as stable for 60 or more days by previous records, except for an isolated calcified granuloma or apical pleural thickening, shall be isolated and evaluated by a clinician even if asymptomatic.

#### Patients with Positive IGRA or TST Assays

Patients with a new positive IGRA test or TST shall have a CXR to assess for radiographic evidence of active TB disease within 72 hours of positive result. If the CXR has no radiographic evidence of active TB disease and the patient is asymptomatic, consider treatment for latent TB infection. Patients with HIV, recent exposure to someone with infectious TB disease, and other high-risk conditions are considered to have a positive TST if there is induration of ≥5 - 9 mm, for everyone else a positive is considered ≥ 10 mm.

High risk conditions include the following:

- HIV-infection or has an unknown HIV infection status;
- Organ transplant and is on transplant immunosuppression; or
- Is otherwise immunosuppressed (e.g., receiving the equivalent of ≥15mg/day of prednisone for ≥ one month, chemotherapy for cancer, or TNF-alpha antagonists—etanercept, infliximab, adalimumab, etc.)

#### Documented Prior Positive IGRA test or positive TST

Patients with written documentation of a positive IGRA test or a positive TST shall:

- Have a CXR within 72 hours of arrival and further workup as clinically indicated to rule-out TB disease.
- Be encouraged to accept treatment for LTBI if previous treatment was incomplete or inadequate. A consult to the Curry Center may be considered if there is concern about the appropriateness of offering therapy.

#### Documented Prior TB Disease

Patients with history of prior TB disease shall be evaluated by a health care provider; and should have a baseline CXR ordered within 3 working days of the health care provider visit.

#### CXR Consistent with Active TB disease

If the CXR has abnormalities consistent with TB, the patient shall wear a surgical mask and be sent to the TTA to be evaluated for TB disease. Please see **Section III Diagnosis of Tuberculosis** for more detail.



## Screening and Surveillance for Tuberculosis, cont'd

### D. Annual TB Evaluation and Testing Program

The Annual Patient TB Evaluation and Testing Program complies with Penal Code (PC) Sections 7570 to 7576, which mandate annual and additional medically necessary screening and evaluation of all patients for TB.

Annual evaluation for TB includes:

1. Evaluation in the birth month of each patient or as soon as possible if patient's screening was delayed (e.g., patients who were OTC during their birth month).
  - Each month, institutional Public Health Nurses or their designees are responsible for using the TB registry to identify which patients need to be screened.
  - The TB registry can be sorted by patients whose annual screening is due or overdue.
  - The TB registry also indicates the type of nursing visit (Licensed Vocational Nurse [LVN] visit or Registered Nurse [RN] visit) required for each patient based on their TB status (see Table 2 Annual Evaluation Requirements Based on TB Status below).
2. Documentation of visits should be completed within the TB Screening Evaluation Report or Tuberculosis Skin Test (TST) Reading in Cerner/EHRS.
3. If symptoms are present patients shall:
  - Wear a surgical mask;
  - Be referred to the Testing and Triage Area (TTA) to be evaluated for active TB disease.

Section I Table 2. Annual Evaluation Requirements Based on TB Status

Patient TB Status	Required
<b>NO LTBI or LTBI TREATED</b> Patients with <ul style="list-style-type: none"> <li>• No documented (latent) TB infection or</li> <li>• (latent) TB infection that is documented as completely treated</li> </ul>	<b>Annual</b> Medical assistant (MA), licensed vocational nurse (LVN), or psychiatric technician (PT) evaluation including: <ul style="list-style-type: none"> <li>• Screening for symptoms of (active) TB disease</li> </ul>
<b>RECENT LTBI, NOT TREATED</b> Patients with (latent) TB infection <ul style="list-style-type: none"> <li>• Diagnosed less than 2 years ago</li> <li>• No documented completion of (latent) TB infection treatment</li> </ul>	<b>Monthly</b> Registered Nurse (RN) evaluation including: <ul style="list-style-type: none"> <li>• Screening for symptoms of (active) TB disease</li> <li>• Education on (active) TB disease</li> <li>• Counseling to seek medical attention if they develop symptoms of (active) TB disease</li> <li>• Encourage treatment for LTBI</li> <li>• If patient declines LTBI treatment, document refusal</li> <li>• Receive a CXR every 6 months throughout the first 2 years post-diagnosis</li> </ul>
<b>REMOTE LTBI, NOT TREATED</b> Patients with (latent) TB infection <ul style="list-style-type: none"> <li>• Diagnosed more than 2 years ago</li> <li>• No documented completion of (latent) TB infection treatment</li> </ul>	<b>Annual</b> RN evaluation including: <ul style="list-style-type: none"> <li>• Screening for symptoms of (active) TB disease</li> <li>• Education on (active) TB disease</li> <li>• Counseling to seek medical attention if they develop symptoms of (active) TB disease</li> <li>• Encourage treatment for LTBI</li> <li>• If patient declines LTBI treatment, document refusal</li> </ul>

## Screening and Surveillance for Tuberculosis, cont'd

Section I Table 2. Annual Evaluation Requirements Based on TB Status, cont'd

Patient TB Status	Required Evaluation
<b>LTBI ON TREATMENT</b> Patients with (latent) TB infection and currently receiving treatment	<b>Annual</b> RN evaluation including: <ul style="list-style-type: none"> <li>• Screening for symptoms of (active) TB disease</li> <li>• Education on (active) TB disease</li> <li>• Education on possible adverse effects of treatment and encourage to complete treatment</li> </ul> Note: These patients are also receiving treatment monitoring as required by the treatment prescribed.
<b>TB TESTING REFUSED – RECENT</b> Patients <ul style="list-style-type: none"> <li>• Whose current incarceration began <b>less than 2 years ago</b> and refused the New Arrival IGRA/TST Test and have not had any subsequent testing.</li> </ul>	<b>Monthly</b> RN evaluation including: <ul style="list-style-type: none"> <li>• Screening for symptoms of (active) TB disease</li> <li>• Education on (active) TB disease</li> <li>• Counseling to seek medical attention if they develop symptoms of (active) TB disease</li> <li>• Offer IGRA/TST Testing</li> <li>• If patient declines testing, document refusal</li> <li>• Receive a CXR every 6 months throughout the first 2 years post-diagnosis</li> </ul>
<b>TB TESTING REFUSED -REMOTE</b> Patients <ul style="list-style-type: none"> <li>• Whose current incarceration began more than 2 years ago; and</li> <li>• Refused the New Arrival IGRA/TST Test and have not had any subsequent testing.</li> </ul>	<b>Annual</b> RN evaluation including: <ul style="list-style-type: none"> <li>• Screening for symptoms of (active) TB disease</li> <li>• Education on (active) TB disease</li> <li>• Counseling to seek medical attention if they develop symptoms of (active) TB disease; and</li> <li>• Encourage/Offer IGRA/TST Testing</li> <li>• If patient declines testing, document refusal</li> </ul>
<b>LTBI STATUS UNKNOWN</b> Patients who have <ul style="list-style-type: none"> <li>• No IGRA/TST result since current incarceration and</li> <li>• No refusal of new arrival IGRA/TST or</li> <li>• IGRA test result indeterminant</li> </ul>	<b>Annual</b> PHN review and evaluation including: <ul style="list-style-type: none"> <li>• Chart Review to clarify Status and update appropriately</li> <li>• Screening for symptoms of (active) TB disease</li> <li>• Education on (active) TB disease</li> <li>• Counseling to seek medical attention if they develop symptoms of (active) TB disease</li> <li>• Offer or repeat IGRA/TST Testing if needed</li> <li>• If patient declines testing, document refusal</li> </ul>
<b>HISTORY OF TB DISEASE, TREATED</b> Patients who have a history of (active) TB disease and have completed treatment	<b>Annual</b> RN evaluation includes: <ul style="list-style-type: none"> <li>• Screening for symptoms of (active) TB disease AND</li> <li>• Education on (active) TB disease</li> </ul>

Section I Table 2. Annual Evaluation Requirements Based on TB Status, cont'd

Patient TB Status	Required
<b>TB CONFIRMED ON TREATMENT</b> Patients with (active) TB disease currently receiving treatment	<b>Annual</b> review, the RN should: <ul style="list-style-type: none"> <li>• Screen for recurrent or worsening symptoms of (active) TB disease</li> <li>• Education on (active) TB disease</li> <li>• Education on possible adverse effects of treatment and encourage to complete treatment</li> </ul> Note: These patients are also receiving treatment monitoring as required by the treatment prescribed.
<b>TB CONFIRMED NOT ON TREATMENT or HISTORY OF TB DISEASE NOT ON TREATMENT</b> Patients with a diagnosis of (active) TB Disease but no documented treatment  <b>Note this status is likely an error but these patients should be evaluated immediately and referred to the PHN for a chart review.</b>	<b>Immediate</b> PHN review and evaluation including: <ul style="list-style-type: none"> <li>• Ensure the patient is masked and placed in airborne isolation</li> <li>• Immediate symptom evaluation and provider referral as needed</li> <li>• Chart Review to clarify Status and update appropriately</li> </ul> If PHN review determines this status is an error, communicate with provider to update the chart which will update the registry, and may remove patient from isolation.
<b>TB SUSPECT ON TREATMENT</b> Patients currently under evaluation for possible (active) TB Disease and taking treatment  OR <b>TB SUSPECT NOT ON TREATMENT</b> Patients currently under evaluation for possible (active) TB Disease not on treatment	<b>Annual</b> review: patient should be seen by the PHN for: <ul style="list-style-type: none"> <li>• Screening for worsening of symptoms of (active) TB disease</li> <li>• Education on (active) TB disease</li> </ul> Note: These patients are awaiting diagnosis and should be actively followed by the health care provider and PHN to determine diagnosis and treatment course.
<b>UNCLASSIFIED</b> Patients who have test results that conflict with historical TB status (e.g., TB codes)  <b>Note this status is likely an error but these patients should be evaluated immediately and referred to the PHN for a chart review</b>	<b>Annual</b> PHN review and evaluation including: <ul style="list-style-type: none"> <li>• Chart Review to clarify Status and update appropriately</li> <li>• Screening for symptoms of (active) TB disease</li> <li>• Education on (active) TB disease</li> <li>• Counseling to seek medical attention if they develop symptoms of (active) TB disease</li> </ul>

## E. Screening Patients Returning from Out to Court, Transfers, and Category S Patients

This includes all patients returning from Out to Court (OTC), or who have been transferred from one institution to another, and patients transferring to California Department of State Hospitals, or en-routers (short stay patients) who are en route to another institution. This also includes all Category S patients (e.g., patients transferred into state institutions from county and city jails). All patients in the above categories will have symptom screening for TB disease immediately upon arrival.

## Screening and Surveillance for Tuberculosis, cont'd

### Asymptomatic

- Patients who return from OTC (even after spending  $\geq 1$  night in a jail), transfer between institutions, or who are short stay patients with no known recent exposure to a patient with TB disease should have symptom screen.
- Asymptomatic category “S” patients without known exposure to TB disease should have symptom screen.

### Symptomatic

- All patients with symptoms or signs of TB shall wear a surgical mask and be sent to the TTA to be evaluated for active TB disease. Workup will include medical evaluation and a CXR and sputum smears and cultures for AFB. When indicated, symptomatic patients will be isolated per clinician order.
- Contact the sending institution to obtain additional available medical information.
- HIV infected patients with symptoms suggestive of TB shall be required to wear a surgical mask and shall be evaluated by a Primary Care Provider (PCP), regardless of CXR findings.

## F. Screening in Special Situations

### Pregnant Patients

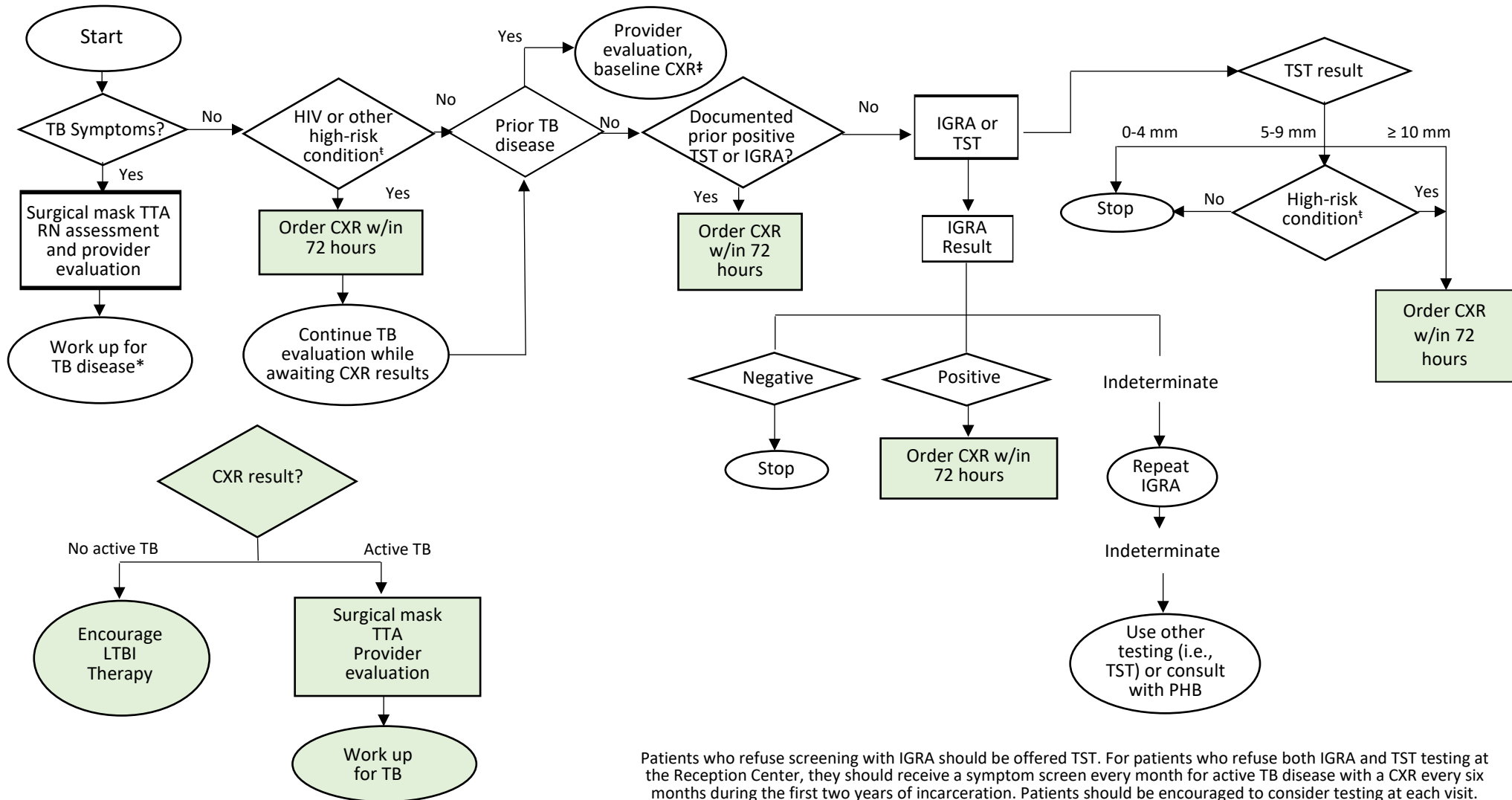
- Testing with IGRA or TST has no adverse effects on pregnancy.
- Pregnancy shall not exclude a person from receiving an IGRA test or TST.
- All pregnant people shall be screened for signs and symptoms of TB disease.
- If the TST is negative, the TST shall be repeated 6 to 12 weeks postpartum.

Proper precautions should be taken to shield the abdomen from the effects of radiation during CXR; some providers may opt to wait until the second trimester to obtain a CXR if the patient does not have symptoms. When indicated in pregnancy, the CXR shall be repeated after delivery. During pregnancy and the first six weeks postpartum, the risk of progression from TB infection to TB disease is high and these patients shall be monitored closely for symptoms of TB disease.

### Patients on Immunosuppressive Medications

Patients who will be starting on immunosuppressive medications (e.g., TNF-alpha antagonists, high dose steroids, chemotherapy) should be screened for TB prior to beginning therapy including both symptom screen and IGRA. Persons with a history of TB infection (LTBI) should be referred for possible treatment prior to starting an immunosuppressive regimen. Certain clinical circumstances may warrant increased efforts to detect TB infection such as a plan to initiate immunosuppressive treatment (e.g., TNF-alpha antagonists), so health care providers may consider performing both IGRA and TST for these patients. The sensitivity of detecting TB infection may be increased when both tests are used.

## Section I Figure 1 Reception Center Screening and Surveillance Decision Tree



Patients who refuse screening with IGRA should be offered TST. For patients who refuse both IGRA and TST testing at the Reception Center, they should receive a symptom screen every month for active TB disease with a CXR every six months during the first two years of incarceration. Patients should be encouraged to consider testing at each visit.

\*Work up for TB disease – Medical evaluation, CXR, sputum smears and cultures for acid fast bacilli

†High-Risk condition

- Has had recent contact with a person with active TB (all contacts in a contact investigation);
- Has abnormalities on a CXR consistent with old TB disease;
- Is HIV-infected or has an unknown HIV infection status;
- Has had an organ transplant and is on transplant immunosuppression; or
- Is otherwise immunosuppressed (e.g., receiving the equivalent of  $\geq 15$  mg/day of prednisone for  $\geq$  one month, chemotherapy for cancer, or TNF – alpha antagonists).

‡Baseline CXR is a chest x-ray taken after TB infection is identified for which a reading is available in CDCR. This †CXR could have been taken many years in the past. A new CXR is not necessary unless there is a positive symptom screen, new positive TB test, or if starting new LTBI.

§LTBI Rx – follow current treatment guidelines

## Section II. Patient Refusals in Screening for Tuberculosis

### A. Patients who are suspected to have (active) TB disease

Per Penal Code Section 7573, the Chief Medical Executive must ensure that patients have an examination or test for TB “upon incarceration and at least annually thereafter.” If a medical officer has a reasonable suspicion that a patient has active TB disease or was recently exposed to active TB disease the patient may be ordered to undergo evaluation to ensure the safety of others in addition to appropriate isolation. Per Penal Code Section 7574, patients who refuse to submit for an exam or treatment, can be tested or treated involuntarily. Title 15 section 3999.210 also discusses the rights of patients to refuse treatment with the exception for tuberculosis testing and treatment. Finally, the CDCR Department Operations Manual Section 51020.12.1 Controlled Use of Force without Extraction discusses issues of involuntary testing or treatment for TB.

Patients presenting with symptoms that may indicate (active) TB disease shall be placed in respiratory isolation and clinically evaluated. If the patient is reasonably suspected of being infected with active TB disease and the patient refuses the order for isolation, the patient shall be isolated involuntarily.

To ensure compliance with Penal Code to prevent TB transmission within CDCR, patients who refuse either the TB screening on entry to CDCR, or during the CCHCS annual evaluation (during birth month), must be referred for further evaluation to determine next steps.

If a patient refuses to comply with initial assessment or symptom screening, the patient should be referred to a provider for further assessment and counseling of the need for TB screening within CCHCS. If the patient continues to refuse despite counseling by the care team, consideration should be given for mental health concerns. Patients who are currently being seen by a mental health provider should be referred to the provider for further discussions. If the patient continues to refuse testing for active disease or treatment, the patient shall be advised the CME is authorized to have testing and medically necessary treatment done involuntarily if suspected of having active TB disease.

### B. Patients who are not suspected of having (active) TB disease:

TB tests (i.e., IGRA tests and TSTs) do not correlate with infectiousness. Therefore, patients who are not suspected of having active TB disease should not be involuntarily tested for TB infection with a TST or IGRA. A medical hold is not necessary for purposes of restricting movement of asymptomatic patients who refuse TB testing.

## Section III: Diagnosis of (Active) Tuberculosis

### A. Screening for (Active) TB Disease

The majority of patients with (active) TB disease have pulmonary infection and will have signs and symptoms characteristic of pulmonary disease. However, TB disease can occur in almost any anatomical location, in multiple discrete anatomical locations, or patients may present with disseminated disease. Therefore, providers assessing patients for (active) TB disease should perform the following:

1. Assess for signs/symptoms and duration of illness.
  - Patients should be assessed for the following symptoms: cough of two to three weeks or more duration, chest pain, hemoptysis, and systemic symptoms (e.g., night sweats, fever, chills, unexplained weight loss, fatigue, anorexia, lymphadenopathy). Please note that patients with extrapulmonary disease may present with hematuria, headache, back pain, hoarseness, etc. depending upon site of disease.
  - Review documentation of patient’s weight to look for weight loss.

## Diagnosis of (Active) Tuberculosis, cont'd

2. Obtain medical history, with special attention to risk factors for TB disease:
  - History of TB exposure, prior IGRA results, tuberculin skin tests (TSTs), prior documentation of TB infection or disease;
  - Place of birth—the majority of TB patients in California were born outside the US;
  - Medical conditions that increase the risk for developing TB disease if infected include the following: HIV or other immunosuppressive conditions; organ transplant recipients; recent diagnosis of TB infection (< 2 years); fibrotic changes on chest x-ray consistent with old/healed TB; diabetes mellitus; silicosis; chronic renal failure; leukemia/lymphoma; carcinoma of the head, neck, or lung; underweight; gastrectomy/jejunoileal bypass);
  - Prior TB infection or disease treatment—completion of therapy, method of administration (e.g., directly observed therapy);
  - Immunosuppressive therapy (equivalent to  $\geq 15$  mg prednisone/day for one month or more); TNF-alpha antagonist therapy; or other immunomodulating medications;
  - Risk factors for drug resistant TB (history of incomplete treatment or immigration from an MDR TB endemic region);
3. Perform physical examination. A physical examination cannot be used to confirm or rule out TB disease but may provide valuable information about the overall condition of the patient and possible site of infection.
  - Assess for signs of pneumonia, pleural effusion, lymphadenopathy, and meningitis or other concerns.
4. Test for TB infection with an interferon gamma release assay (IGRA) or tuberculin skin test (TST). IGRAs are strongly preferred for most patients, particularly if they are non-U.S. born, because of specificity of test compared to TST. Please note a TST or IGRA may be negative in the setting of active disease.
5. Obtain chest imaging:
  - The chest x-ray must be completed within 72 hours of suspicion of TB disease and must include posterior-anterior (PA) and lateral views.
  - The chest x-ray report(s) must be forwarded to the institution's Chief Medical Executive (CME)/designee for review and recommendations with a "wet reading" (immediate impression) by the ordering physician.
  - Radiographic abnormalities are often seen in the upper lobe (apical and posterior segments) or lower lobe superior segments. Lesions may appear anywhere in the lungs and may differ in size, shape, density, and cavitation.
  - With HIV or other condition causing immunosuppression, the CXR may be typical, atypical, or with no visible lesions. Typical cavitory lesions are usually observed in patients with higher CD4 counts (e.g., above 500 cells/mm<sup>3</sup>). Atypical patterns are observed in patients with lower CD4 counts, including infiltrates in any lung zone, mediastinal and/or hilar adenopathy, or occasionally, a normal CXR.
  - In patients with HIV and symptoms and signs of TB disease, a negative CXR does not exclude TB disease.
  - Note, the presence of mixed nodular and fibrotic lesions on CXR may signify "old" TB disease. These lesions may contain slowly multiplying tubercle bacilli and have the potential for progression to TB disease. Persons who have "old" TB disease on a CXR and have a positive TST reaction or positive IGRA result should be considered high-priority candidates for treatment for TB infection (LTBI), but only after TB disease is excluded because "old" TB cannot be differentiated from infectious (active) TB disease based on CXR appearance alone. Conversely, fully calcified, discrete, nodular lesions without fibrosis likely represent granulomas and pose a lower risk for future progression to TB disease. Additionally, extrapulmonary TB — which is more common in HIV patients may have a normal CXR.



## Diagnosis of (Active) Tuberculosis, cont'd

6. Obtain HIV test if the last HIV test was more than 6 months prior to this TB evaluation.
7. If CXR, TST, IGRA, or other findings concerning of (active) TB disease—the patient will require additional laboratory testing to rule out active pulmonary disease.
  - Collect respiratory specimens for all patients in whom pulmonary, pleural, or laryngeal TB is suspected, as well as in those in whom extrapulmonary TB has been diagnosed.
8. For institutions where TB rule out may occur in house, providers may utilize the Suspect TB Powerplan to order all laboratories, imaging, and follow up visits.

### Section III: Table 1 Work Up of a Patient Suspected of (Active) TB Disease

Patient	Work Up
Cough 2 or more weeks or other symptoms like fever, night sweats, weight loss, or hemoptysis	Perform CXR. If concerning perform sputum collection.
Patient with unexplained illness including respiratory symptoms for more than 2 weeks	Perform CXR. If concerning perform sputum collection.
HIV patient with unexplained cough or fever	CXR and three sputum specimens and NAAT
Patient with community acquired pneumonia that is not improving	CXR and three sputum specimens, and NAAT
Patient with CXR findings concerning for TB	Review prior imaging; obtain 3 sputum cultures, one NAAT

Adapted from Diagnosis of pulmonary tuberculosis in adults—UpToDate

## B. Collection of Respiratory Sputum Specimens

Specimens must be collected with the patient isolated in an AIIR. The initial laboratory evaluation of respiratory specimens for all suspect TB patients requires all of the following:

- Collection of three respiratory specimens for AFB smear and culture.
- Specimens must be collected **>8 hours but <24 hours apart**. While it is necessary to ensure 8-hour intervals between specimens, it is not necessary to collect at longer intervals—24-hour collection intervals are not advisable and lead to unnecessarily long AIIR stays.
- Coughing is the most commonly used method of sputum collection. Coughing should be supervised to ensure that sputum is collected correctly. A health care worker wearing the recommended personal protective equipment shall coach and directly supervise the patient when sputum is collected.
- For patients unable to cough up sputum, deep sputum-producing coughing may be induced if there are no contraindications to induced sputum collection. This must be performed in an AIIR by inhalation of an aerosol of warm, sterile, hypertonic saline (3%–5%).
- One of the specimens must be collected:
  - in the early morning (preferred),
  - by sputum induction (second choice), or
  - by bronchoalveolar lavage (BAL) (last choice).
- Nucleic acid amplification testing (NAAT) of one of the respiratory specimens. The NAAT should be performed on an AFB positive smear, if available.



## Diagnosis of (Active) Tuberculosis, cont'd

- One of the specimens must be tested by NAAT even if all smears are AFB negative. (When all AFB smears are negative, any of the specimens may be chosen for NAAT testing, however, it is preferable to test the specimen that was collected in the early morning, by sputum induction, or by BAL).
- Please see Section III Table 1 TB Laboratory Results and Subsequent Actions for interpretation or AFB smears/NAAT testing and next steps.

Culture results may take up to 6 weeks to return. Monitor for return of culture results as TB disease may be present even if smear and NAAT results were negative. Culture examinations should be done on all diagnostic specimens, regardless of AFB smear or NAAT results. MTB can grow in culture specimens that were AFB smear and NAAT negative. Culture is much more sensitive than smears to diagnose TB disease.

- 5,000 to 10,000 bacilli per milliliter of specimen are required for detection of bacteria in stained smears.
- In contrast, 10 to 100 bacilli are needed for a positive AFB culture result. Thus, patients with TB disease may have negative AFB smears with a subsequent positive culture.

Please note that negative AFB smears do not exclude TB disease. A single negative NAAT result should not be considered to definitively exclude TB disease, especially when the clinical suspicion of TB disease is moderate to high.

## C. Additional Microbial Testing

If extrapulmonary TB is suspected, in addition to sputum specimens, clinical specimens (e.g., urine, cerebrospinal fluid, pleural fluid, pus, or biopsy specimens) may also be submitted for examination as dictated by the history and clinical exam.

## D. Culture Negative (Clinically Confirmed) TB Disease

In the absence of a positive culture, TB disease may be diagnosed on the basis of clinical signs and symptoms alone. The diagnosis is often based on the clinical response to TB treatment.

- The Local Health Department (LHD) TB Controller must be consulted when respiratory specimen cultures from a high suspect TB patient are negative for MTB.
- It is the LHD TB Controller's responsibility to decide if the patient's clinical signs and symptoms warrant a diagnosis of clinically-confirmed TB. The patient's TB medications must not be discontinued before the LHD TB Controller thoroughly reviews the patient's clinical course.

## E. Drug Susceptibility Testing

For patients with positive mycobacterial tuberculosis complex (MTB) cultures, phenotypic drug-susceptibility testing and genotyping is required. Drug susceptibility testing for first-line MTB drugs must be performed on at least the first isolate from MTB positive sputum cultures. If testing demonstrates resistance to first-line TB drugs, second-line drug susceptibility testing must be performed. In addition to conventional testing, some patients may require rapid testing for genes that may confer resistance to TB medications.

Rapid molecular testing is especially important for patients with:

- Prior TB disease treatment; or
- Contact with a patient with known anti-TB drug resistant disease; or
- On current TB therapy not responding to treatment; or

## Diagnosis of (Active) Tuberculosis, cont'd

- Residence for  $\geq 1$  year in a country with a high primary MDR-TB incidence. A list of countries with high primary MDR-TB prevalence can be found at <https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2022/tb-disease-burden/2-3-drug-resistant-tb#fig--2-3-6>.

Higher prevalence countries generally include Angola, Botswana, Burma, Chad, China, Democratic People's Republic of Korea, Ethiopia, India, Kenya, Indonesia, Malawi, Mozambique, Namibia, Nigeria, Pakistan, Peru, Philippines, Republic of Moldova, Russian Federation, South Africa, Tanzania, Thailand, Uganda, Ukraine, Uzbekistan, Vietnam, Zambia, and Zimbabwe.

A limitation of molecular testing for drug resistance is that the clinical relevance of some of the mutations identified in MTB genes remains unknown. Therefore, it is essential that conventional (growth-based/phenotypic) drug-susceptibility tests are done in conjunction with molecular testing. Providers should call CCHCS PH for help in locating a reference laboratory for rapid molecular testing for drug resistance if drug resistance is suspected (e.g., because the patient had incomplete TB treatment the past).

### Section III Table 2. TB Laboratory Results and Subsequent Actions

AFB smear results (3 specimen)	NAAT results (1 specimen)	Next Steps	Culture Results	Next Steps
<b>Low Suspect TB</b>				
Negative	Negative for MTB	May consider release from AIIR if all conditions of the low suspect protocol are met	Negative for MTB	No further workup necessary
Negative	Negative	May consider release from AIIR if all conditions of the low suspect protocol are met	Positive for MTB	Start patient on RIPE, Consult TB Controller and CCHCS Public Health
Negative	Positive	Move to high suspect, smear negative below	Negative for MTB	Consult TB Controller and CCHCS Public Health
Negative	Positive	Move to high suspect, smear negative below		
>1 Positive	Positive	Move to high suspect, smear positive below		
<b>High Suspect*</b>				
Negative	Negative for MTB	Start patient on 4 drug therapy (if no concern for MDR TB <sup>†</sup> )	Negative for MTB	Seek consultation with TB Controller and CCHCS Public Health
Negative	Negative for MTB	Start patient on 4 drug therapy (if no concern for MDR TB <sup>†</sup> )	Positive for MTB	Continue TB regimen
Negative	Positive for MTB	Start patient on 4 drug therapy (if no concern for MDR TB <sup>†</sup> )	Positive for MTB	Continue TB regimen
Negative	Positive for MTB	Start patient on 4 drug therapy (if no concern for MDR TB <sup>†</sup> )	Negative for MTB	Seek consultation with TB Controller and CCHCS Public Health
$\geq 1$ Positive	Negative for MTB	Start patient on 4 drug therapy (if no concern for MDR TB <sup>†</sup> ) and consult with TB controller	Negative for MTB	Seek consultation with TB Controller and CCHCS Public Health

AFB smear results (3 specimen)	NAAT results (1 specimen)	Next Steps	Culture Results	Next Steps
<b>High Suspect* cont'd</b>				
≥1 Positive	Negative for MTB	Start patient on 4 drug therapy (if no concern for MDR TB†)	Positive for MTB	Continue TB regimen
≥1 Positive	Positive for MTB	Start patient on 4 drug therapy (if no concern for MDR TB†)	Negative for MTB	Seek consultation with TB Controller and CCHCS Public Health
≥1 Positive	Positive for MTB	Start patient on 4 drug therapy (if no concern for MDR TB†)	Positive for MTB	Continue TB regimen

\*High Suspect TB patients should be placed on empiric 4 drug therapy (e.g., rifampin, isoniazid, pyrazinamide, ethambutol) while work up ongoing.

†If patient has exposure to multi-drug resistant TB (MDR TB), consult the TBCB and LHD TB Controller.

## F. IGRA and Tuberculin Skin Tests (TST)

IGRA and TST assays identify if a person's immune system recognizes the TB antigen. They do not differentiate between latent TB infection and active TB disease, and they may be falsely negative in patients with TB disease. For persons with a recent exposure, the IGRA or TST may not become positive for 8-10 weeks after the exposure.

An IGRA is a blood test that measures T-cell release of interferon-gamma after stimulation by MTB antigens. There is no cross-reactivity for patients who have a history of Bacille Calmette-Guérin (BCG) vaccine, and it may be more sensitive in individuals who are immunocompromised. IGRA results are reported as positive, negative, or indeterminate.

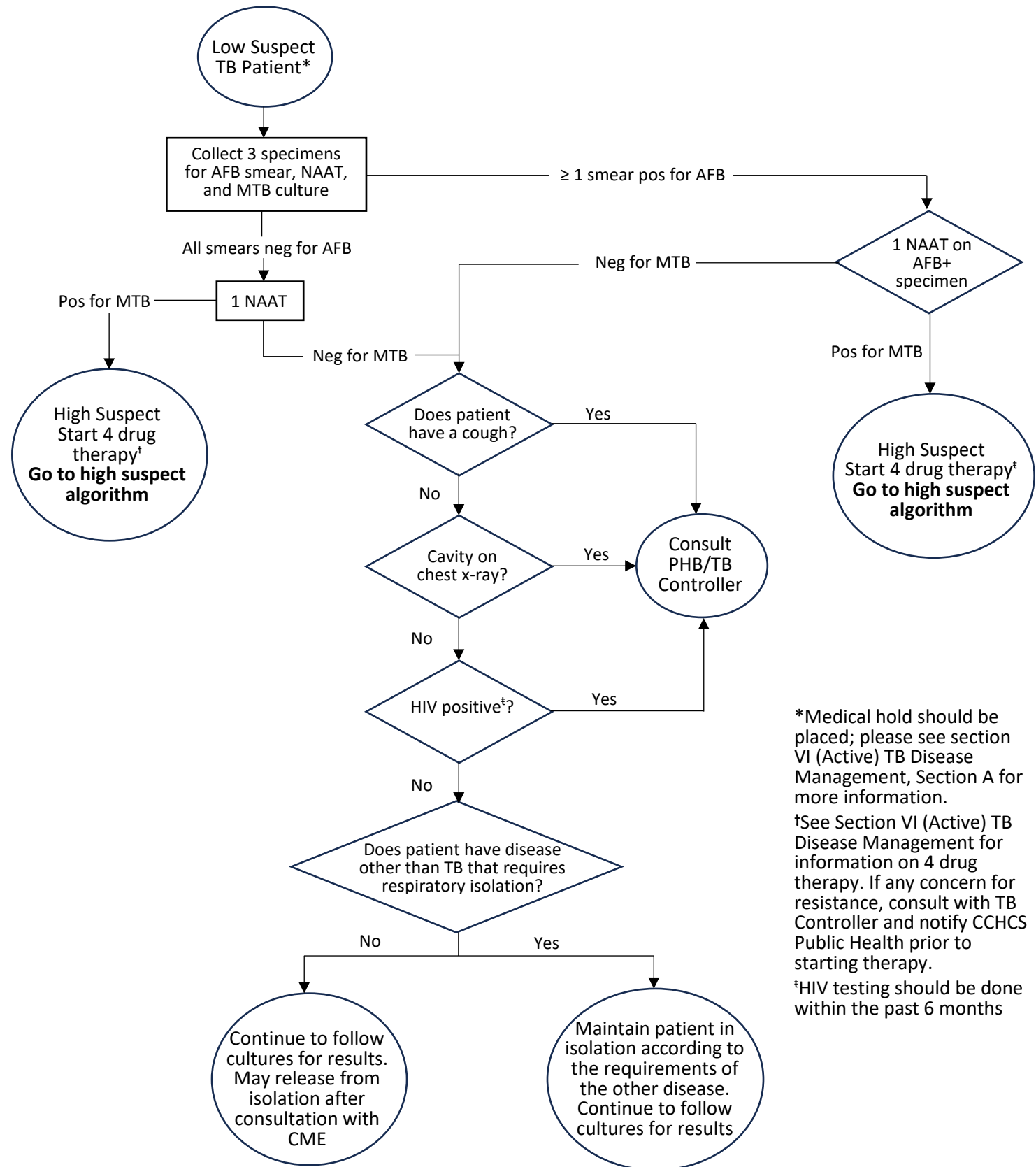
For a TST, a small amount of purified protein derivative tuberculin antigen is placed intradermally on the forearm. After 48 to 72 hours the size of the transdermal swelling (induration and not erythema) is measured to determine if a TST is positive. The PPD tuberculin antigen stimulates a delayed-type hypersensitivity response. The TST is not as specific as an IGRA as persons with a history of BCG vaccine or non-mycobacterial infection may have a positive result. Generally, adverse reactions are rare, but some patients may have immediate hypersensitivity. For persons who require serial testing, TST may be better than an IGRA given issues with reproducibility and reversion.

Patients with TB infection or latent tuberculosis infection (LTBI) have either a positive TST or a positive IGRA test, are infected with *Mycobacterium tuberculosis* (MTB), but do not have TB disease, are not infectious and cannot spread TB to others.

### Section III Table 3. Interpretation of a Positive TST by Induration Measurement

≥5 mm	≥10 mm
<ul style="list-style-type: none"> <li>• People living with HIV</li> <li>• A recent contact of a person with active TB disease</li> <li>• Chest x-ray findings suggestive of previous TB disease</li> <li>• Organ and hematopoietic stem cell transplant recipients</li> <li>• Other immunosuppressed people (e.g., patients on prolonged therapy with corticosteroids equivalent to/greater than 15 mg per day of prednisone or those taking TNF-alpha antagonists)</li> </ul>	<ul style="list-style-type: none"> <li>• People who live or work in high-risk congregate settings (e.g., in correctional facilities)</li> </ul>

## Section III Figure 1. Low Suspect TB Evaluation Algorithm

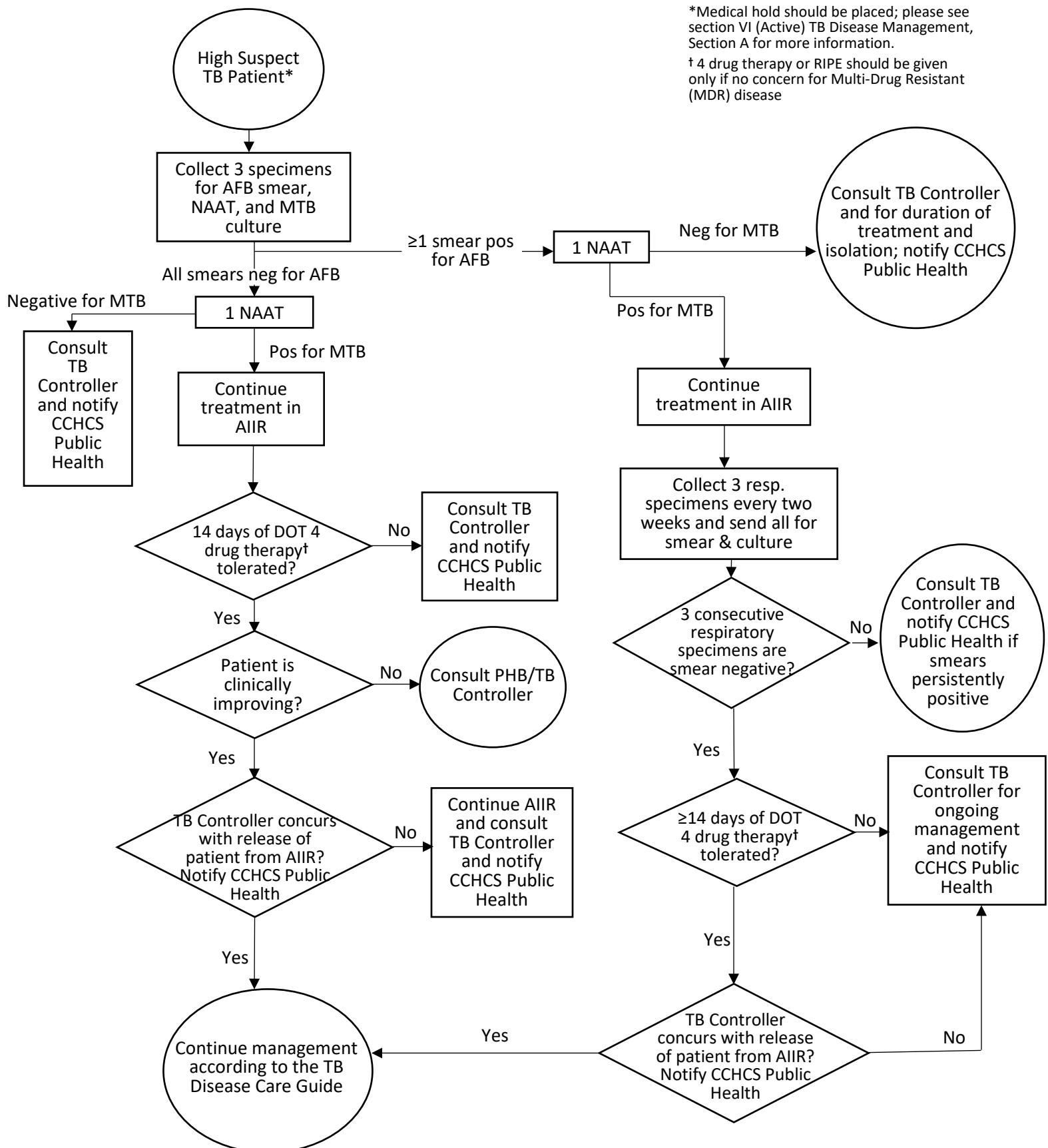


\*Medical hold should be placed; please see section VI (Active) TB Disease Management, Section A for more information.

†See Section VI (Active) TB Disease Management for information on 4 drug therapy. If any concern for resistance, consult with TB Controller and notify CCHCS Public Health prior to starting therapy.

‡HIV testing should be done within the past 6 months

## Section III Figure 2. High Suspect TB Evaluation Algorithm



## Section IV: Isolation and Movement

All patients with suspected (active) TB disease should be immediately given a procedure mask and rapidly isolated in an airborne infection isolation room (AIIR) with airborne precautions instituted.

### A. Airborne Isolation Procedures

Every patient under Airborne Precautions should be transferred to an AIIR as soon as possible. If an AIIR is not immediately available, the patient should remain in a room with solid walls and a closed solid door and transported as soon as possible to an AIIR.

#### Personal Protective Equipment (PPE)

Staff/Volunteers: all staff in contact with a patient under Airborne Precautions, including staff guarding, transporting, or caring for a patient, must wear fit-tested and NIOSH approved respiratory protection with a protection level of an N95 mask or higher, like a powered air purifying respirator (PAPR).

Patient requirements for airborne precautions include wearing a surgical mask covering the nose and mouth if leaving or outside an AIIR for any reason (e.g., during transportation within a facility such as moving from a housing unit to a clinic, during transportation to another institution or a contract hospital). While in an AIIR, the patient need not wear a mask. If the surgical mask becomes moist or torn it must be changed.

### B. Patient Movement Issues

#### Patient Movement Within Facility

Patients requiring Airborne Precautions who are transferred within an institution (e.g., from a housing unit to the medical clinic), the receiving area *must* be notified prior to the patient's arrival that airborne precautions are required.

#### Patient Movement Outside the Facility

If the patient is transferred to another institution for AIIR placement, the CME/designee of the institution where the patient is isolated becomes the responsible CME.

A patient under Airborne Precautions poses a high risk of transmitting TB Infection and cannot be put on regular CDCR transportation, including buses and transportation used to move incarcerated people from CDCR facilities. These residents shall be transferred by special transportation using respiratory precautions. Medical staff will alert the receiving institution or hospital of the transfer of a patient needing Airborne Precautions.

Please note, affected institution staff (medical and custody) will be informed of the indicated exposure precautions following the policy per Health Care Department Operations Manual 3.8.8, Communicating Precautions from Health Care Staff to Custody Staff.

## Isolation and Movement, cont'd

### Release from Isolation

Releasing a patient from respiratory isolation depends upon a number of factors that influence a patient's infectiousness and risk to others. These factors include any the following:

- Location of active TB disease in lungs, airways, or larynx,
- Presence of a cough,
- Presence of an AFB positive respiratory smear,
- Extent of infiltration on chest x-ray,
- Presence of a cavity on chest x-ray, or
- Duration of appropriate treatment.

### Release from Isolation Criteria

#### Low Suspect TB:

Patients who are low suspect TB are patients with lower clinical suspicion for (active) TB disease and are not started on empiric 4 drug RIPE therapy.

A low suspect TB patient may be released from respiratory isolation if **all** the following conditions are met:

- The patient does not have a cough,
- The chest x-ray (or other imaging) is negative for cavitory disease,
- The patient does not have another infectious disease that requires respiratory isolation,
- The patient is not HIV infected (with a negative HIV test documented within the past 6 months),
- There have been three respiratory specimens collected and sent for culture (please see Section III Diagnosis of [Active] Tuberculosis for more information),
- All respiratory specimens were smear negative for acid fast bacilli (AFB), or any smear positive respiratory specimen was nucleic acid amplification test (NAAT) negative for MTB,
- A NAAT has been performed on one specimen and is negative for *Mycobacterium tuberculosis* (MTB) DNA, and
- There is consultation and concurrence with the CME or designee of the institution. The CME may get consultation from CCHCS PH as needed.

Note: To release low-suspect patients that do not have all criteria met, there must be a review by the TB Controller from the Local Health Department (LHD) with a written recommendation from the TB Controller or designee (e.g., county health officer or communicable disease controller).

#### High Suspect TB

Patients with high suspect (active) TB disease cannot be released from isolation without permission from the LHD TB Controller. These patients have a high clinical suspicion of active TB disease and are started on empiric 4 drug TB therapy.

Specific criteria for release of high suspect TB patient depends on results of pulmonary testing including AFB smear and NAAT result. All required specimens must be sent with AFB smear and NAAT results returned prior to consideration for release. Please see Table 1. Release Criteria for High Suspect Patients Without Risk Factors for Multi-Drug Resistant (MDR) TB for more detail.

## Isolation and Movement, cont'd

**Section IV Table 1. Release Criteria for High Suspect Patients Without Risk Factors for MDR TB**

Criteria	Required for release
All smears negative; NAAT negative	<ul style="list-style-type: none"> <li>• Patient has taken and tolerated 5 or more days of 4 drug therapy or RIPE (Rifampin, Isoniazid, Pyrazinamide, Ethambutol) via directly observed therapy (DOT)</li> <li>AND</li> <li>• Consultation and concurrence with the LHD TB Controller and CCHCS PH</li> <li>AND</li> <li>• Clinical improvement</li> </ul>
Smear negative, NAAT positive	<ul style="list-style-type: none"> <li>• Patient has taken and tolerated 5 or more days of 4 drug RIPE therapy via DOT</li> <li>• Consultation and concurrence with the LHD TB Controller and CCHCS Public Health</li> <li>AND</li> <li>• Clinical improvement</li> </ul>
Smear positive, NAAT negative	<ul style="list-style-type: none"> <li>• Consult with CCHCS PH and LHD TB Controller to determine if patient can be released without further treatment</li> <li>OR</li> <li>• After 14 days of RIPE</li> <li>AND</li> <li>• Clinical improvement</li> </ul>
Smear positive, NAAT positive (or unknown)	<ul style="list-style-type: none"> <li>• Three subsequent specimens collected by the TB respiratory specimen collection protocol were AFB smear negative,</li> <li>• The patient has taken and tolerated 14 days RIPE delivered by DOT,</li> <li>• The patient has clinically improved,</li> <li>AND</li> <li>• There is consultation and concurrence with the LHD TB Controller and CCHCS PH;</li> <li>AND</li> <li>• Clinical improvement</li> </ul>

### High Suspect TB with Risk Factors for Multi-Drug Resistant (MDR) TB

Patients with MDR TB or suspected MDR TB may be released from respiratory isolation only after thorough review by the MDR TB treatment team led by the California Department of Public Health (CDPH) TB Control Branch (CB).

## Section V: Tuberculosis Infection Treatment (Latent Tuberculosis Infection)

Once a patient has been determined to have LTBI or TB infection and has ruled out for (active) TB disease, including symptom screen and chest x-ray, it is recommended that patient be treated for LTBI to prevent progression to (active) TB disease. If there is any suspicion of (active) TB disease, 3 respiratory specimens must be collected for AFB smear/culture, and nucleic acid amplification, and all cultures must be negative before treatment for TB infection (LTBI) is started.



## Tuberculosis Infection Treatment, cont'd

Patients with TB infection or LTBI have either a positive tuberculin skin test (TST) or a positive Interferon-Gamma Release Assay (IGRA) test, are infected with *Mycobacterium tuberculosis* (MTB), but do not have active tuberculosis (TB disease), are not infectious and cannot spread TB to others.

ALL patients with TB infection should be considered as candidates for TB infection treatment.

**Section V Table 1. When to Consider TB Infection (LTBI) Treatment Based on Medical History, Exposure to TB Disease, and IGRA/TST Results**

Medical Conditions	IGRA +	TST <5mm	TST ≥5mm	TST ≥10mm
Persons with known exposure to a patient with TB disease and who are immunocompromised*, defined as: <ul style="list-style-type: none"> <li>HIV-infected or unknown HIV status (not tested in the past 6 months); or</li> <li>Treatment with the equivalent of ≥15 mg/day of prednisone for ≥one month; or</li> <li>Cancer chemotherapy; or</li> <li>TNF-alpha antagonist treatment; or</li> <li>Immunosuppressive treatment for an organ transplant.</li> </ul>	Treat	Treat*	Treat	Treat
Persons who are not immunocompromised with known exposure to a patient with TB disease	Treat	Do Not Treat	Treat	Treat
Immunocompromised (as defined above) and no known TB exposure	Treat	Do Not Treat	Treat	Treat
Patients with old fibrotic lesions on chest imaging and 3 negative respiratory cultures and no known TB disease exposure	Treat	Do Not Treat	Treat	Treat
Patients with no known immunosuppression and CXR normal or consistent with old, healed TB (pleural thickening, calcified nodule, or calcified lymph nodes) and no known TB exposure	Treat	Do Not Treat	Do Not Treat	Treat

\*Immunocompromised patients with a known exposure to a person with TB disease should be treated for TB infection even if the TST is < 5mm.

### A. Preferred Regimens for TB Infection (LTBI)

Currently there are four main treatment regimens for TB infection treatment that are recommended by the Centers for Disease Control and Prevention (CDC) and endorsed by the National TB Controllers and Curry Center. Other LTBI regimens may be approved prior to future updates of this care guide and providers are encouraged to look at the CDC [website](#) for most up to date information. Providers may discuss potential regimens with the Curry Center, the California Department of Public Health TB Control Branch (TBCB), the Local Health Department or CCHCS Public Health. Please see table 2 for current treatment regimens.

## Tuberculosis Infection Treatment, cont'd

Antiretroviral therapy (ART) for HIV may have several interactions with TB infection regimens and providers must ensure no drug-drug interactions when choosing an appropriate regimen. Rifabutin may be used in some situations to replace rifampin as there are fewer drug-drug interactions. However, there is limited data on rifabutin. Rifabutin cannot be substituted for rifapentine. Patients on INH based regimens should have pyridoxine supplementation of 25-50 mg daily to prevent neuropathy.

If a patient has already been treated, re-treatment may be indicated for patients at high risk of becoming re-infected and progressing to TB disease (e.g., immunosuppressed patients).

With known exposure to TB, a full course of TB infection treatment may be recommended even in the absence of a positive test for TB infection. Consult with CCHCS PH and the LHD regarding the management of such contacts.

Providers may utilize the EHRS Latent TB Infection Powerform to order TB medications, laboratories, and follow-up visits.

Please see **Appendix C Tuberculosis Medications** and the [Curry Center Rifamycin Drug-Drug interactions website](#) for more information. The interactions listed are not exhaustive and providers should consult drug-interaction databases and consult with pharmacy prior to prescribing.

### Section V Table 2. TB Infection (LTBI) treatment Regimens: Doses, Frequency/Duration, Completion, and Contraindications

Priority Rank*	Regimen	Dose	Frequency/Duration	Total doses/completion	Contraindications	Frequency of Monitoring	Comments
Strongly Preferred	3 months isoniazid (INH) plus Rifapentine (3HP)	INH: 15 mg/kg (900 mg maximum) Rifapentine: 25.1-32.0 kg, 600 mg 32.1-49.9 kg, 750 mg, 50 or more kg, 900 maximum	Once weekly/3 months	12 /within 16 weeks	<ul style="list-style-type: none"> <li>• Hepatitis C on treatment†</li> <li>• Pregnancy</li> <li>• Warfarin† (Coumadin)</li> <li>• Anti-epileptic therapy†</li> <li>• Patients with advanced liver disease‡</li> <li>• Hyper-sensitivity to INH or rifamycins</li> <li>• Patients with exposure to INH or rifamycin resistant TB</li> <li>• Some HIV ART medications have critical drug-drug interactions</li> </ul>	Monthly RN visits	In the event of a national shortage of rifapentine, providers are encouraged to ensure availability of all 12 doses prior to starting patients on this regimen.

Section V Table 2. LTBI treatment Regimens: Doses, Frequency/Duration, Completion, and Contraindications, cont'd

Priority Rank*	Regimen	Dose	Frequency/Duration	Total doses/completion	Contraindications	Frequency of Monitoring	Comments
Strongly Preferred	4 months rifampin (4R)	10 mg/kg maximum dose 600 mg	Daily, 4 months	120 doses/within 6 months	<ul style="list-style-type: none"> <li>• HIV on ART</li> <li>• Allergy to rifamycins</li> </ul>	Monthly RN visits	
Preferred	3 months INH plus rifampin (3HR)	INH 5 mg/kg, 300 mg maximum, rifampin 10 mg/kg, 600 mg maximum	Daily, 3 months	90/ within 4 months	<ul style="list-style-type: none"> <li>• Advanced liver disease†</li> <li>• Acute active hepatitis</li> <li>• Chronic hepatitis with LFTS &gt;5 x ULN</li> <li>• Hyper-sensitivity to INH</li> <li>• Heavy or daily alcohol use</li> <li>• Some HIV ART medications have critical drug-drug interactions</li> <li>• Allergy to rifamycins</li> </ul>	Monthly RN visits	
Alternative	6 months INH (6H)	15 mg/kg maximum 900 mg	Twice weekly	52/within 9 months	<ul style="list-style-type: none"> <li>• Advanced liver disease†</li> <li>• Acute active hepatitis</li> <li>• Chronic hepatitis with LFTS &gt;5 x ULN</li> <li>• Hypersensitivity to INH</li> <li>• Heavy or daily alcohol use</li> </ul>	Monthly RN visits	For patients with fibrotic lesions on CXR, 9 month is preferred
Alternative	9 months INH (9H)	15 mg/kg, maximum 900 mg	Twice weekly	76/within 12 months	<ul style="list-style-type: none"> <li>• Advanced liver disease†</li> <li>• Acute active hepatitis</li> <li>• Chronic hepatitis with LFTS &gt;5 x ULN</li> <li>• Hyper-sensitivity to INH</li> <li>• Heavy or daily alcohol use</li> </ul>	Monthly RN visits	Preferred regimen for patients with fibrotic lesions on chest imaging

\*Based on CDC Guidance

†Relative Contraindications

‡Advanced liver disease – patients with elevated liver function tests 3 x upper limit of normal (ULN), elevated total bilirubin (&gt;2.0), prolonged international normalized ratio (INR), prothrombin time (PT, or partial thromboplastin time (PTT). Isoniazid is contraindicated in these patients and providers may consider the 4R regimen.

## Tuberculosis Infection Treatment, cont'd

### B. Provider Evaluation: Before Starting TB Infection (LTBI) Therapy

All patients should be ruled out for active TB disease prior to beginning LTBI treatment.

1. For patients with signs or symptoms consistent with active TB disease, LTBI treatment must not be started until:
  - Cultures for MTB from three respiratory specimens return negative, and
  - The patient is deemed not to have clinically confirmed TB disease.
2. All drug interactions must be evaluated prior to prescribing treatment for TB infection.
3. Patients should have the following baseline laboratories completed prior to starting a LTBI regimen:
  - Baseline liver function tests (LFTs) i.e., AST, ALT, and bilirubin, HIV, HBsAg, and HCV tests.
  - Obtain LFTs every month only for patients with any past adverse reaction to INH or rifampin, abnormal baseline LFTs, chronic liver disease including cirrhosis, chronic HCV or HBV infection, excessive alcohol use, hepatic disease, injection drug use, Dilantin or valproic acid treatment, pregnancy or within 3 months after delivery.
  - Consider monthly CBC for patients with history of anemia or other hematological issues.
  - Laboratory testing should also be performed to evaluate possible adverse reactions that occur during the treatment regimen including CBC and complete metabolic panel.
4. Patients should be counseled on signs and symptoms of hepatotoxicity, thrombocytopenia, and other adverse effects and told to present immediately for evaluation should they arise.
  - Mild or moderate adverse effects (rash, dizziness, fever) should be conservatively managed (e.g., dizziness can be treated with rest or oral fluids) and LTBI treatment should NOT be discontinued.
5. Discontinue treatment for TB infection if:
  - LFT is  $\geq 5$  times the upper limit of normal even if the patient has no symptoms of hepatotoxicity; or
  - LFT is  $\geq 3$  times the upper limit of normal and the patient has symptoms of hepatotoxicity.
6. Severe adverse reactions (e.g., hepatotoxicity, hypotension requiring intravenous fluid support), treatment for LTBI should be discontinued and patients treated appropriately, (e.g., referred to a higher level of care).
  - Severe adverse events (e.g., liver injury, metabolic acidosis, anaphylaxis, seizure, severe dermatitis) with hospitalization or death must be reported immediately to the FDA and the local health department. To report events to the FDA, clinicians may submit a MedWatch alert.
  - If discontinuation of TB infection therapy is required, alternative regimens can be considered in consultation with an Infectious Diseases specialist or the Curry Center.
7. Providers are encouraged to utilize the Latent TB Infection Power Form to order medications.
8. Providers must also ensure that the patient's problem list is updated to include (latent) TB Infection.

### C. Monitoring on TB Infection (LTBI) Therapy

Licensed Vocational Nurses (LVNs) shall administer TB infection treatment by direct observation (directly observed therapy [DOT]).

Patients should be assessed for any adverse reactions (please see table 3 below) and referred to an RN for a focused evaluation that day. *Please note:* If a patient presents with fever, yellow eyes, dizziness, rash, or aches or greater than 1 day of nausea, vomiting, weakness, abdominal pain, or loss of appetite, then TB infection treatment should be discontinued, and the patient should be referred to the TTA.

## Tuberculosis Infection Treatment, cont'd

1. Patients shall be seen by an RN monthly to:
  - Assess for adherence, tolerance to treatment, TB signs or symptoms and adverse effects. Please see Section V table 3 for adverse reactions and Section V table 4 regarding required monitoring while on treatment;
  - Obtain blood pressure (to assess for hypotension) and weight (to check for weight loss);
  - Review laboratory results and refer those with abnormal tests to a provider;
  - Report any findings consistent with TB disease or adverse effects to a provider; and
  - Educate the patient on TB infection, symptoms of TB disease and adverse drug effects, and encourage the patient to seek prompt medical attention if he/she develops symptoms;
  - Encourage the patient to complete treatment for TB infection;
  - Record treatment completion on the problem list.
2. Within 30 days of the end of treatment patients should be seen by their provider to:
  - review treatment completion,
  - ensure adherence,
  - discuss any adverse effects,
  - other concerns regarding TB infection and risk for later TB disease,
  - and to document resolution on the problem list.

### Section V Table 3. Potential Adverse Reactions of TB Infection (LTBI) Medication Regimens

- |  |                             |
|--|-----------------------------|
| • Numbness or tingling in hands/feet                 | • Weight loss               |
| • Headache   | • Abdominal pain/tenderness |
| • Seizure  | • Diarrhea                  |
| • Vision changes                                     | • Dizziness                 |
| • Memory loss  | • Fever or chills           |
| • Appetite loss                                      | • Rash (+/- hives)          |
| • Nausea/vomiting                                    | • Sore muscles or joints    |
| • Jaundice: yellow skin or eyes, brown or dark urine | • Easy bleeding or bruising |
|  | • Fatigue                   |

### Section V Table 4. Required Monitoring While on TB Infection (LTBI) Treatment

	Regimen	How often
Adherence and tolerance of regimen	All	• Each RN visit
Any active TB disease symptoms	All	• Every time seen by LVN or RN
Adverse Reactions	All	• Every LVN and RN visit
Weight	All	• Every RN visit
Blood Pressure	All	• Every RN visit
Laboratory Monitoring*	All	• Monthly LFTS, and CBC† reviewed by providers and RN at each RN visit. Any abnormalities should be forwarded for review and consultation with the provider.
Education on TB symptoms, adherence	All	• Every RN visit

\*LFT monitoring may be more frequent for patients with hepatic disease or elevated LFTs at baseline

† CBC may be indicated if patients have known hematologic disorders or complain of rash or easy bruising

## Tuberculosis Infection Treatment, cont'd

### D. Special Situations

#### ***Pregnancy:***

After TB disease is excluded, consider treatment for TB infection if the pregnant woman is HIV infected or recently exposed to a person with TB disease. Otherwise, delay initiating treatment for TB infection until 2-3 months post-partum as there is increased risk of hepatotoxicity through the first 3 months post-partum). 4R (rifampin monotherapy) is the shortest and most well tolerated for pregnant patients. INH based regimens should be used with caution given the concern for hepatotoxicity. Pregnant patients on INH therapy must receive pyridoxine supplementation.

#### ***Interrupted Treatment:***

Completion of therapy is based on the total number of doses administered - not on the duration of therapy. If treatment is not completed within the recommended timeframe, extend treatment until completed—consult with the Curry Center or CCHCS Public Health.

If there is a significant treatment interruption, refer patients to a provider for a TB sign and symptom review, physical examination, and when indicated, a CXR and bacteriologic studies to exclude active TB disease prior to restarting latent TB infection treatment. After a LTBI treatment interruption of more than six months a CXR is required. Providers may also consider a consultation with Curry Center and CCHCS Public Health as needed.

### E. Monitoring Patients Not on TB Infection (LTBI) Therapy

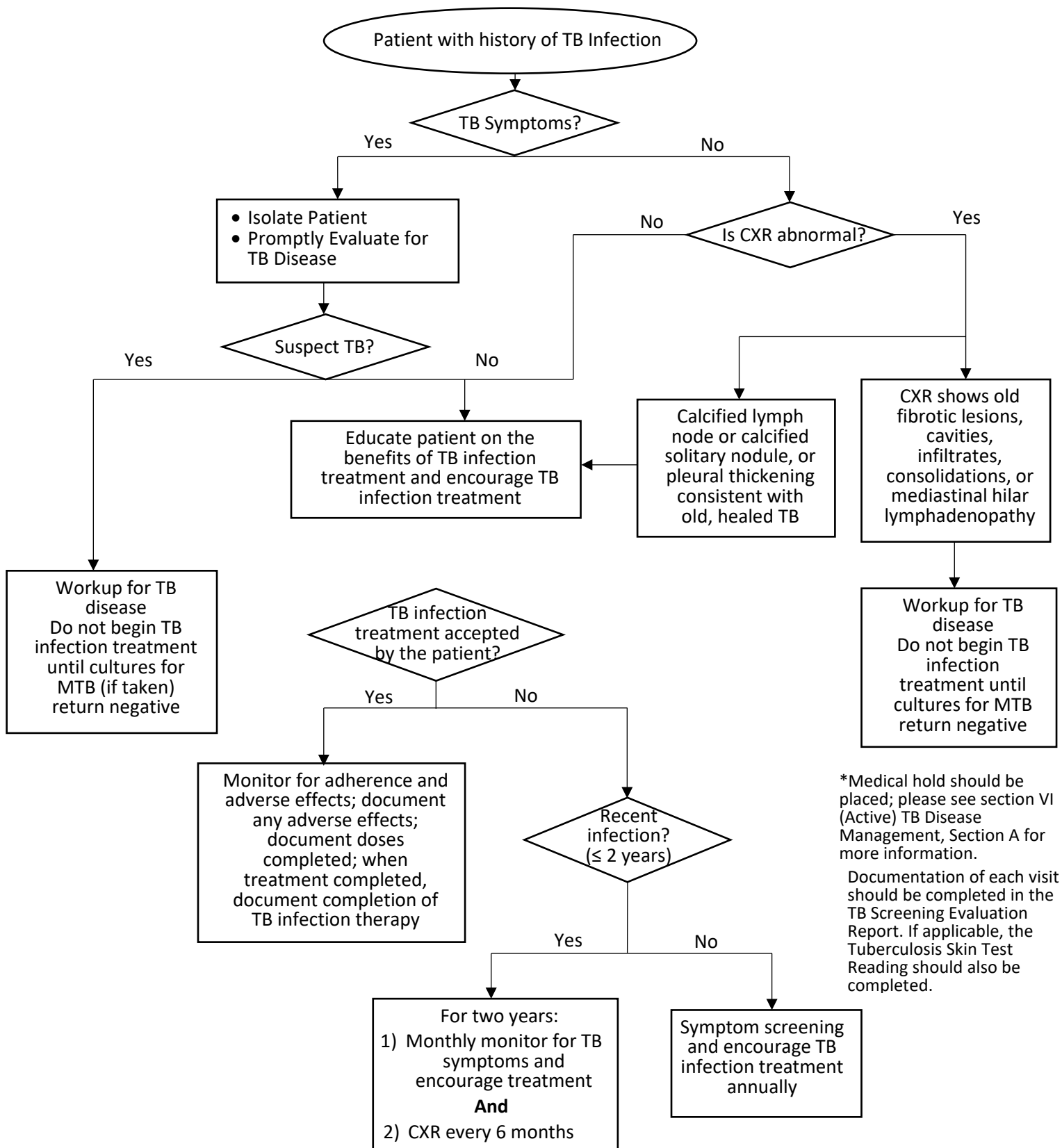
For patients with a history of recent infection (<2 years) without documentation of TB Infection treatment or incomplete treatment, these patients will require monthly signs and symptoms review and education. Patients should be encouraged at each visit to start TB Infection treatment. Additionally, patients will need a CXR every 6 months.

For patients with a history of remote infection (≥2 years) with incomplete or no TB infection treatment, they should have an annual visit for evaluation of TB signs and symptoms, education on TB disease, and encouragement of TB infection treatment.

Patients who have documented completion of TB infection treatment should be screened annually for signs and symptoms of TB disease.

Please see Section I table 2 for more detail.

## Section V Flow Chart: TB Infection (LTBI) Evaluation Algorithm



\*Medical hold should be placed; please see section VI (Active) TB Disease Management, Section A for more information.

Documentation of each visit should be completed in the TB Screening Evaluation Report. If applicable, the Tuberculosis Skin Test Reading should also be completed.

## Section VI: (Active) Tuberculosis Disease Management

### A. Background

The goals of treatment for TB disease include decreasing the bacterial load, decreasing the risk of transmission, preventing further complications of infection including extrapulmonary dissemination, and death. Treatment for active TB disease should be started immediately in high suspect or confirmed TB patients. Low suspect TB patients should be started on therapy when TB disease is confirmed.

Patients who are being treated for TB disease should be identified as high risk on the medical classification chronology (MCC) for duration of the course of treatment. Providers must record medical hold on the MCC (to permit retention at institution for completion of TB therapy when medically appropriate).

Patients with suspected or confirmed active TB disease should be managed by a TB care team. The TB care team members should include at a minimum:

- Chief Medical Executive (CME)/designee and/or Chief Physician and Surgeon (CP&S)/designee
- Chief Nurse Executive (CNE)/designee
- Providers and nursing staff with primary medical responsibility for the patient
- Public health nurse (PHN)
- Utilization management (UM) nurse
- CCHCS Public Health
- The Associate Warden Health Care Services/designee
- Pharmacist in charge/designee

TB medications, especially rifamycins (e.g., rifampin, rifabutin, rifapentine) can interact with other medications. Providers should account for potential drug interactions prior to prescribing an MTB treatment regimen and should consult detailed prescribing information to review all potential drug-drug interactions, contraindications, and other precautions. If there are any contraindications or other reasons why a patient with pan-sensitive pulmonary disease may not receive a first line regimen please consult the Curry Center, the California Department of Public Health TB Control Branch (TBCB), and the LHD for an alternate regimen. Alternate regimens must have proper documentation within the patient chart. Additionally, please alert CCHCS Public Health.

Providers should utilize the Active TB Disease Powerform in Cerner/Electronic Health Record System to order medications, laboratory, and follow up monitoring appointments.

Please see **Appendix C Tuberculosis Medications** and the [Curry Center Rifamycin Drug-Drug interactions website](#) for more information on drug interactions, contraindications, and note that providers should utilize drug information databases and consult with pharmacy for additional information.

### B. Communication

Prior to the patient being discharged from the institution, paroled, or released while on TB treatment, or if the patient is a suspect TB and not yet started on therapy, the CME must notify the LHD and CCHCS Public Health of the planned discharge/release or parole:

- A written treatment plan has been received and approved by the LHD,
- The LHD of the jurisdiction to which the patient is paroling/releasing or discharging is notified, and
- If a patient is being discharged to a local detention facility, the chief medical officer of that facility must receive and accept the written treatment plan.



**(Active) Tuberculosis Disease Management, cont'd****C. Pan-Sensitive Pulmonary Tuberculosis**

The preferred regimen for pan-sensitive pulmonary active TB disease includes only first line medications. First line drugs include rifampin (RIF), isoniazid (INH), pyrazinamide (PZA), and ethambutol (EMB). Other short course and alternate regimens are available (e.g., rifapentine, moxifloxacin), however, there are significant limitations to which patients are eligible as well as medication availability. It should be noted that medications must be appropriately dosed for weight—underdosing may lead to treatment failure and development of drug resistance. Treatment duration is determined by imaging and laboratory findings—please see Table 1 below.

All TB medications for TB disease should be given at the same time (no splitting doses) via directly observed therapy (DOT) 7 days per week. Patients should be educated on all side effects and told to report adverse effects immediately.

**Section VI Table 1. Preferred Regimen for Pulmonary Active TB Disease—Pan-Sensitive**

Patient findings	Initiation Phase	Continuation phase	Treatment Completion
No cavitary lesions on CXR or other imaging; and culture negative respiratory specimens (taken 8 weeks on treatment)	INH: 5 mg/kg daily 300 mg maximum dose, 300 mg daily is usual dose for adult patients RIF: 10 mg/kg 600 mg maximum dose, 600 mg daily is the usual dose for adult patients PZA*: please see Appendix C. for detailed weight-based dosing guidelines EMB†: please see Appendix C. for detailed weight-based dosing guidelines Vitamin B6‡: 25-50 mg daily for 8 weeks (56 doses)	INH/RIF + B6‡ daily for 18 weeks (126 doses) <sup>§</sup>	Total duration therapy 26 weeks (182 total doses) <sup>§</sup>
Cavitary lesions on CXR or other imaging; or culture positive respiratory specimens (taken 8 weeks on treatment)	As above	INH/RIF + B6‡ daily for 28 weeks (196 doses) <sup>§</sup>	Total duration therapy 36 weeks (252 total doses) <sup>§</sup>

\*PZA is contraindicated in the following patients: pregnant patients, patients with active gout or severe liver disease. For these patients an alternate 39-week regimen should be discussed with the treatment team, the LHD TB controller and CCHCS Public Health.

†Ethambutol should be discontinued as soon as laboratory results indicate that the MTB is pan-sensitive.

[Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis | Clinical Infectious Diseases | Oxford Academic \(oup.com\)](#)

‡ For patients with peripheral neuropathy, consider 100 mg vitamin B6 (pyridoxine) daily.

§ First line TB medications should be given as a single dose by DOT. Split doses should be avoided.

## (Active) Tuberculosis Disease Management, cont'd

### D. Resistance

Resistant disease may be classified as primary drug-resistant disease or laboratory-confirmed drug resistant TB in a patient with no prior history of TB treatment, and acquired drug-resistant disease or laboratory-confirmed drug resistant TB in a patient whose isolate develops drug resistance after an unsuccessful course of treatment. Drug-resistant TB disease must always be treated with a daily regimen and under DOT.

The CME must immediately consult the LHD TB Controller, the CDPH TBCB, and may also consult with the Curry Center when patients with drug resistant disease are identified: including for patients with monoresistant disease (resistant to either INH or RIF) in addition to multidrug (MDR) and extensively drug resistant TB (XDR TB).

Multidrug resistant (MDR) TB is resistant to both INH and RIF. These patients are at high risk for treatment failure, relapse, further acquired resistance, or death, as well as adverse drug events. These patients will be treated with three to five second line agents that show activity *in vitro*.

Extensively drug resistant TB (XDR TB) is a rare type of MDR TB that is resistant to INH and RIF, as well as any fluoroquinolones, and at least one of 3 injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin). This rare circumstance requires immediate notification of the LHD TB Controller and the CDPH TBCB.

Management of resistant TB shall proceed according to the recommendations of the TBCB.

### E. Special situations

#### ***Culture negative TB:***

For patients with smear and culture-negative TB, the California TB Controllers Association (CTCA) recommends a longer duration of therapy in the continuation phase than do national guidelines. The CTCA guidelines stipulate that patients with smear and culture-negative TB who are responding to therapy after 2 months and for whom no other etiology is identified, should continue treatment for an additional 4 months (for a total of 26 weeks and 182 doses of treatment). In addition, because of the high level of INH resistance in California, the CTCA guidelines recommend the continuation of at least 3-drug therapy with INH, RIF, and EMB throughout the continuation phase of treatment. Consultation with the CDPH TBCB or Curry Center should be obtained.

#### ***Extrapulmonary Tuberculosis:***

Extrapulmonary TB disease is generally managed in the same way as pulmonary TB. Empiric therapy should not be delayed, particularly for central nervous system (CNS) disease. A 6-month regimen (2 months on INH, RIF, PZA and EMB followed by 4 months of INH and RIF), unless the organisms are known or suspected of being resistant to first-line drugs. The exception to this recommendation is TB disease involving the CNS, for which up to 12 months of therapy is recommended. Response to treatment must often be measured by clinical and radiographic findings rather than by culture because of the relative inaccessibility of the sites of disease.

**(Active) Tuberculosis Disease Management, cont'd**

Providers should consult the Curry Center and/or the TB CB to discuss initial regimens to ensure that regimens chosen have adequate penetration into the CNS.

***Patients Living with HIV:***

Patients with HIV infection and TB have a higher likelihood of:

- Paradoxical reactions, which may be misinterpreted as clinical worsening;
- Concomitant illnesses or infections that may complicate treatment;
- Drug resistance and drug interactions; and
- Malabsorption of drugs.

As with all treatment of TB disease in CCHCS patients, daily dosing of TB medications is required. Every effort should be made to use a rifamycin-based regimen for the entire course of TB therapy in HIV-infected patients. The drug-drug interactions between the rifamycins and antiretroviral drugs must be managed appropriately, rather than using TB treatment regimens that do **not** include a rifamycin or by withholding antiretroviral therapy until completion of TB treatment. Rifabutin (sometimes with dose adjustments) may be substituted for rifampin when a patient is on antiretroviral therapy in some situations. These patients should be co-managed with an Infectious Diseases specialist to ensure an appropriate regimen.

***Pregnant or Breastfeeding Patients***

Untreated TB disease represents a greater hazard to a pregnant woman and her fetus than does TB treatment. A three-drug, nine-month regimen with INH, RIF, and EMB can be used in pregnant women who are HIV negative. Pyrazinamide may be considered in some situations. Streptomycin is the only anti-TB drug documented to have harmful effects on the human fetus (congenital deafness) and it should not be used. Consultation with an Infectious Diseases specialist and close collaboration with obstetrics-gynecology should be pursued for pregnant women requiring active TB disease treatment.

Because of the unknown risk of second-line drugs to the fetus, pregnant women being treated for TB disease on second-line drugs should be counseled accordingly and expert consultation should be sought with the TBCB and Curry Center.

***Patients with Co-Morbid Hepatic Disease***

Patients may be at increased risk for hepatotoxicity secondary and should be monitored closely for signs of toxicity. These patients may require co-management with an Infectious Diseases and Hepatology specialist.

***Patients with Co-Morbid Renal Insufficiency***

TB medication doses and/or frequency of administration may need to be altered for patients with renal insufficiency or ESRD or patients on dialysis. Drug levels may need to be monitored.

**F. Monitoring**

Patients with smear positive pulmonary disease must have 2 respiratory specimens collected and sent for AFB smear and culture every 7 days. These should be collected greater than 8 hours but less than 24 hours apart. Patients should have weekly specimens collected until they return smear negative. At that point patients may have respiratory specimens collected every two weeks (2 specimens collected between 8 and 24 hours apart) until cultures are consistently negative—or at least two sets of negative cultures with sets collected 7 days apart.

**(Active) Tuberculosis Disease Management, cont'd**

If cultures remain positive at three months of treatment, or if the patient clinically or radiographically fails to improve or worsens, drug susceptibility testing should be performed on clinical isolates to assess for resistance.

**Section VI Table 2. Clinical, Laboratory and Radiographic Monitoring of Patients on treatment for active TB disease**

Time Point	Clinical	Laboratory	Radiographic
Baseline (prior to treatment start)	<ul style="list-style-type: none"> <li>Evaluation for any conditions that place patient at high risk for TB progression or for toxicity from TB medications, e.g., renal insufficiency.</li> <li>Baseline tests for visual acuity (Snellen Chart) and color vision (Ishihara) because EMB has the potential for ocular toxicity manifesting as optic or retrobulbar neuritis.</li> <li>Education regarding possible side-effects of medications, e.g., the possible visual side effects of EMB, and instructions to immediately report signs and symptoms of toxicity to a health care provider.</li> </ul>	<ul style="list-style-type: none"> <li>HIV</li> <li>CD4+ lymphocyte count if HIV+</li> <li>Serum creatinine</li> <li>Platelet count</li> <li>AST, ALT, bilirubin, alkaline phosphatase*</li> <li>HBsAg</li> <li>HCV antibody</li> </ul>	<ul style="list-style-type: none"> <li>CXR or other chest imaging</li> </ul>
During treatment	<p>Weekly RN visits and monthly provider visits to:</p> <ul style="list-style-type: none"> <li>Assess adherence to regimen.</li> <li>Identify adverse reactions.</li> <li>Assess clinical response to treatment.</li> <li>For patients on EMB: ask about visual disturbances including blurred vision or scotomata.</li> <li>Visual acuity test (Snellen chart, monthly, patients on EMB).</li> <li>Color vision test (Ishihara, monthly, patients on EMB).</li> </ul>	<ul style="list-style-type: none"> <li>Sputum: 2 sets weekly, more than 8 hours apart but within 24 hours until persistently smear negative</li> <li>Monthly</li> <li>AST, ALT, bilirubin, alkaline phosphatase*</li> </ul>	<ul style="list-style-type: none"> <li>CXR if clinically worsening</li> </ul>

Time Point	Clinical	Laboratory	Radiographic
End of treatment	<ul style="list-style-type: none"> <li>Patients with MDR TB, recurrent TB, extensive disease, or poor adherence to treatment need more intensive end-of-treatment and post-treatment monitoring (at least monthly).</li> <li>Educate patient on signs and symptoms of recurrence of TB, particularly prolonged cough, fever, and weight loss, and the necessity of immediately reporting these to a health care provider.</li> <li>For pan-sensitive pulmonary disease: bimonthly clinical follow-up for at least 6 months after therapy ends.</li> <li>Document end of treatment in problem list.</li> </ul>	<ul style="list-style-type: none"> <li>2 sputum specimens for AFB culture and smear</li> </ul>	<ul style="list-style-type: none"> <li>CXR to document response to treatment</li> </ul>
<p>*INH, RIF, PZA are all potentially hepatotoxic. Significant liver toxicity is indicated by AST <math>\geq 3X</math> Upper Limit of Normal (ULN) in the presence of symptoms or <math>\geq 5X</math> in the absence of symptoms. In these cases, the LHD TBC should be consulted immediately (before the next treatment dose). Patients with the following conditions and circumstances are at high risk for hepatotoxicity:</p> <ul style="list-style-type: none"> <li>Abnormal baseline liver panel results</li> <li>Liver disease (e.g., HBV, HCV, alcohol abuse)</li> <li>Pregnancy or in the first 3 months postpartum</li> <li>Taking other hepatotoxic medications</li> </ul>			

## G. Treatment Failure

Treatment failure is defined as continued or recurrently positive sputum cultures for  $\geq 3$  months after treatment initiation in a patient receiving adequate drug therapy. In general regimens should be expanded with at least three new drugs that have not been previously used. Single drugs should not be added as this increases risk for resistance.

Treatment failure may be caused by acquired drug resistance resulting from nonadherence to treatment regimens, malabsorption, or advanced HIV disease.

Patients should have an evaluation that should include symptom review, CXR, repeat drug susceptibility testing on positive cultures, clinical assessment for malabsorption, and assessment of potential laboratory error.

Treatment failure should be immediately reported to the LHD TBC, who must approve any change in the treatment regimen. Consultation with another TB expert, e.g., California Department of Public Health (CDPH) TB Control Branch (TBCB) or the Curry Center is required.

**(Active) Tuberculosis Disease Management, cont'd****H. Relapse**

Is defined as a patient who had documented culture conversion during treatment, and throughout the treatment. However, after treatment patient has a positive culture or develops signs and symptoms consistent with active TB. Relapse may be caused by failure to sterilize host tissues, and rarely exogenous reinfection. Risk factors for relapse include advanced HIV disease (based on expert opinion), extensive TB with cavitary disease, and persistent positive sputum cultures 2 or more months after treatment initiation.

In patients previously treated with DOT, relapse generally occurs with organisms having the same susceptibility profile as the pretreatment isolate. Management of these patients should be discussed with a TB expert (e.g., CDPH TBCB or the Curry Center) and the LHD TB Controller.

**Section VII. Contact Investigations****Step 1: Isolation and Reporting****Diagnosis of Active or Suspect Active TB Disease Made Outside an Institution**

When a patient is diagnosed with TB classification Suspect 5 or TB disease, the institution must be immediately notified. This notification may come from the treating hospital, the county, or from the utilization management nurse. The institution's Chief Medical Executive (CME), Chief Physician and Surgeon, Chief Nurse Executive (CNE), and the treating Physician and Surgeon, should be notified.

Coordination and communication with the local health department, and responsibilities of the local health department are outlined in the CDPH and California TB Controllers Association Guidelines for Coordination of TB Prevention and Control by Local and State Health Departments and California Correctional Health Care Services here: <https://ctca.org/wp-content/uploads/2018/11/FinalCorrections2015.pdf>

Upon return to the institution, the patient should be placed on airborne precautions and the CME or designee must immediately notify leadership and custody, including immediately reporting to California Correctional Health Care Services (CCHCS) Public Health (PH). If the institution is not located within the same county as the hospital, the Local Health Department (LHD) of the institution must also be immediately notified by the CME or designee. These requirements are pursuant to Health Care Department Operations Manual Section 3.8.8 Communicating Precautions from Health Care Staff to Custody Staff.

**Diagnosis Made within Institutions**

A patient who is diagnosed with TB classification suspect 5 or TB disease within the institution, the institution leadership should be notified including CME, Chief Physician and Surgeon, CNE, Public Health Nurse (PHN) Infection Control Nurse, and custody, as needed. The PHN is also responsible for notifying the LHD and CCHCS PH.

**Medical Hold:**

If the patient has a positive acid-fast bacilli (AFB) smear from a respiratory specimen that is NAAT-positive (e.g., polymerase chain reaction, GeneXpert, Mycobacterium TB Direct [MTD] or pyrosequencing test), the CME or designee will write orders for medical holds on all close contacts of the patient (index case) until the contacts have been evaluated and determined not to have (active) TB disease. A medical hold may be extended at the discretion of the CME or designee.

**Reporting:**

Mandatory reporting via the Correctional Facility Tuberculosis Plan (CFTP) must be completed and sent to the LHD and CCHCS PH as discussed in Appendix A. Reporting.

## Contact Investigations, cont'd

### Step 2: Notification of Employee Health Program

The Employee Health Program (EHP) should be notified within 72 hours after the TB case is reported to the LHD and CCHCS PH. A CCHCS PH designee must notify and provide exposure information to the EHP designee, while maintaining patient privacy. The EHP is responsible to identify, investigate, notify, document, and provide follow up to employees who are potentially exposed and employees with known exposure from the work environment. The EHP coordinates with the appropriate LHDs and other regulatory agencies to ensure all regulatory compliance is met. For further information, contact the headquarters EHP.

### Step 3: Patient Interview and Case Management

The Institution PHN or designee for institutions with a PHN vacancy is responsible for providing public health management (e.g., reporting and communication with CCHCS PH and LHD) of patients with active TB disease and managing TB contact investigations. The TB contact investigation (CI) forms needed by a PHN for a CI include the following:

- TB Contact Investigation Public Health Nurse Checklist;
- TB Patient Interview Form;
- TB Contact Investigation Line List and TB Contact Investigation Summary Page signed by the CME at the conclusion of the investigation (located as one of the tabs within the Contact Investigation Line List);
- Transferee Follow-up Request Form and/or TB Contact Letter for Institutions form.

The Institution PHN or designee is responsible for collecting patient background information and completing the case patient interview. The TB case patient interview is key to the CI process and requires pre-interview planning and activities by the PHN to:

- Consult with the patient's health care provider to obtain current clinical information.
- Collect patient background information by reviewing the patient's health record.
- Gather names and initiate line lists of patients to be evaluated in phase 1 of the CI described below.
- Begin establishing the infectious period.

The patient interview must take place in a confidential facility setting within three business days of the TB case identification. If the patient is still admitted to a community hospital, the patient interview must occur within five business days, or within seven business days of case identification if located outside of the LHD's jurisdiction. The interview should be conducted in a manner that establishes rapport and build trust with the patient and ensures confidentiality.

During the TB case patient interview, the "TB Patient Interview Form" is completed to obtain the following Information:

- Demographics & personal information
- Medical history
- Symptom history
- Housing (consider ventilation)
- Contacts
- Daily activities (e.g., work or school)
- If infectious period expands to include time prior to incarceration, outside institution contacts (e.g., jail)
- Any prior known TB exposure

## Contact Investigations, cont'd

The PHN:

- Identifies and lists contacts exposed for each listed activity in the Contacts Information section of the “TB Patient Interview Form”.
- Documents approximate number of hours per week for each activity.
  - If the TB case patient is symptomatic, document each activity for up to three months pre-symptom onset.
  - If the TB case patient is asymptomatic, document each activity for up to one month before the date of diagnosis.
- Summarizes the case patient’s interview and makes the information available for the CI team, which includes the LHD and CCHCS PH, either in writing or on the teleconference call. Case patient information shared should have all patient identifiers removed if in a summary report or if presenting on a teleconference call.

### Step 4: Contact Investigation Team Created for Initial Teleconference Call

After a decision is made to initiate a CI teleconference call, a CI Team must be created in the institution that includes the following:

- TB case patient’s health care provider
- CME, Chief Physician and Surgeon
- Chief Nursing Executive (CNE)
- Chief Executive Officer (CEO)
- PHN

The Contact Investigation Team will also include:

- Representative(s) from California Department of Public Health’s Tuberculosis Control Branch’s
- Representative(s) from the local health department: Local Health Officer (LHO) and TB Controller, local health department correctional TB liaison, and/or other appropriate LHD staff members
- CCHCS PH
- Employee Health

A CI clinical teleconference will be scheduled within two business days after the TB case patient interview. The institution PHN, CCHCS PH physician and PH nurse consultant will identify the required teleconference participants. CCHCS PH staff will set up the meeting day and time based on the availability of the key participants. A CCHCS PH physician will be responsible for preparing the agenda and leading the teleconference. The CCHCS PH nurse consultant will work together with the CCHCS PH physician to establish the meeting and ensure meeting minutes are accurately completed.

The teleconference clinical participants will review the TB case patient’s clinical findings and treatment plan, determine the infectious period window start and end dates, and prioritize contact groups (close contacts and immunosuppressed contacts at higher risk of progressing to TB disease), determine if there are any additional contacts which may have been exposed (e.g., jail contacts), and determine next steps for the investigation. The clinical participants will define the criteria for contacts who are high priority. Follow-up meetings, as determined by the CI team, will be scheduled at the end of each teleconference.



## Contact Investigations, cont'd

The CI team teleconference minutes will be completed and distributed by CCHCS PH but must be kept at the institution for official record keeping. Minutes will include information on the CI progress for both the institution's patients and the employees.

### Step 5: Initiate a Contact Investigation

Patient information gathered by the PHN will be evaluated by the CI team participants to determine the exposed and high priority contact groups. The CI team will discuss and make recommendations for the exposed and high priority contact groups to be placed on medical holds along with recommendations for the initiation of exposed contact clinical assessments (e.g., TB sign/symptom review, chest x-ray [CXR] and TB infection treatment initiation, if indicated). Symptomatic contacts must have immediate referral and clinical evaluation regardless of the type of contact or index case characteristics.

#### Guidelines for the Investigation of Contacts Exposed to a Person with Infectious TB:

The index case patient's characteristics: AFB smear, NAAT and CXR results along with the patient's TB signs and symptoms will be used to determine the degree of CI indicated. These data will be used to determine the beginning and end of the infectious period. The three most common scenarios are:

- CI indicated: Infectious period to begin three months prior to symptom onset or first positive findings consistent with TB disease, whichever is longer, or
- CI indicated: Infectious period to begin four weeks prior to date of diagnosis as a confirmed case or presumptive diagnosis as a TB case, or
- CI not indicated.

A decision to initiate a CI will be made for patients with the following results:

- Culture or NAAT-confirmed pulmonary, laryngeal, or pleural TB from a respiratory specimen, **OR**
- Positive AFB smear on a respiratory specimen and NAAT-positive or a NAAT was not done, **OR**
- Three negative AFB smears and one NAAT-positive on a respiratory specimen.

The window period (time required for the TB organism to become detectable after a person is exposed to a person with infectious TB disease) is determined during the CI team teleconference. The window period typically ends 8-10 weeks after the last exposure to the TB case. Please see Table 1 Contact Investigation for California State Prisons.

### Step 6: Development of TB Contact Investigation Line Lists

The PHN will prepare a record of the TB case patient's movement history during the infectious period by location (e.g., housing unit, worksite, classroom, social exposure areas) using information gathered during the chart review and the patient interview. Additional information to note:

- The size of room/areas where exposures occurred,
- Estimated dates of exposure,
- Estimated time/frequency index spent at exposure site,
- Length of contact exposure times.

## Contact Investigations, cont'd

### Step 7: Contact Investigation Phase I

The PHN will develop the high priority immunosuppressed contact and close contact line lists using the criteria and direction recommended by the CI team. The PHN will also prepare a “TB Contact Investigation Line List” for other exposed contacts but not determined to be high risk during the first phase of the CI. The contacts who were not initially considered to be at high risk or significantly exposed as determined in the CI team teleconference will only be screened if the CI expands (table 2).

Within 24 hours after the teleconference, all high priority immunosuppressed contacts should be identified and recorded by location on the “TB Contact Investigation Line List”.

High priority immunosuppressed contacts include:

- HIV-infected
- Had organ transplant and is on transplant immunosuppression
- Otherwise immunosuppressed (e.g., receiving TNF-alpha antagonists or the equivalent of  $\geq 15$  mg/day of prednisone for  $\geq$  one month)
- Chemotherapy for cancer
- Diabetic patients
- Hemodialysis patients
- Children under five years of age if any family visiting

Within two business days after the teleconference, the PHN should complete a “TB Contact Investigation Line List” that includes all high priority contact including those that are close contacts.

The PHN is responsible for requesting printouts of all contacts who were housed in cells or housing units with the TB case patient during the likely infectious period, including those who transferred, paroled, or released. The printouts can be requested from the Classification and Parole Representative (C&PR).

The high priority immunosuppressed contacts and other high priority contacts must have a prompt TB sign/symptom screen and CXR (completed/read), along with an interferon-gamma release assay (IGRA) or tuberculin skin test (TST) placed, if indicated.

- If there is evidence of TB disease, the patient contact must be referred immediately to a health care provider for a clinical evaluation.
- If there is evidence of TB infection (e.g., positive IGRA or TST  $\geq 5$  mm result and no TB sign/symptoms), the patient contact must be referred to a health care provider for a clinical evaluation to rule out TB disease.
- Exposed patient contacts with TB symptoms or a newly positive IGRA or TST must be considered to be TB disease suspects and cannot be treated for TB Infection/Latent TB Infection (LTBI) treatment until TB disease is ruled out by a provider. This rule out requires CXR and may require three documented smear and culture results. After TB disease is ruled out and the patient contact is diagnosed with LTBI, a provider order may order treatment for LTBI.
- LTBI treatment for patient contacts should be highly encouraged and promptly initiated.

## Contact Investigations, cont'd

All exposed high priority contacts should have a recent HIV test (if not documented negative in the past 6 months). HIV tests should be offered using the opt-out screening method.

TB screening must be performed and recorded for all high priority immunosuppressed contacts and other close/significantly exposed contacts. All contact screenings must be recorded on the "TB Contact Investigation Line List" and in the Electronic Health Record System (EHRS) TB Testing Evaluation Report (TB Evaluation and Testing Section).

Contact TB screenings include the following:

- Complete a TB sign/symptom screening
- IGRA or TST on all patients without a prior positive
- HIV test, if not done in past 6 months
- CXR, for immunosuppressed, and contacts with positive IGRA or TST
- Clinical assessment by health care provider for immunocompromised, persons with history of IGRA/TST positive, and any CXR abnormalities

Please review the following flow charts for the process to properly evaluate the patient with these conditions:

- 1) Flowchart 1 for immunocompromised contacts,
- 2) Flowchart 2 for immunocompetent contacts, and
- 3) Flowchart 3 for contacts with prior history of positive IGRA or TST

Any contact who develops TB symptoms must be promptly assessed for TB disease by a health care provider. Contacts with a new positive IGRA or TST indurations  $\geq 5$  mm are considered newly infected. These contacts must have a TB sign/ symptom screen, CXR, and evaluation by a health care provider to rule out TB disease. If TB disease is ruled out, the contact must be assessed for any immunocompromising conditions and whether or not they have previously completed TB infection treatment in order to determine further clinical evaluation and treatment.

Contacts with negative IGRA or TST indurations  $< 5$  mm without TB symptoms are considered to be uninfected and must be re-screened 8-10 weeks after last exposure to the TB case.

The summary results for the ongoing CI can be found within the "TB Contact Investigation Line List" and is the tab labeled "Summary." The summary data is automatically calculated from the patient information entered in the line list. The PHN can provide a detailed report from the information found on the summary page to present to the CI team periodically throughout the CI. The CI team will determine if the CI should be expanded based on documented transmission of disease (e.g., infection rate).

## Step 8: Contact Investigation Phase II

The purpose of Phase II is to re-evaluate for evidence of disease for patients exposed within 8-10 weeks when identified.

Window-period screening: 8-10 weeks after the last exposure to the TB case patient, follow-up must be performed and recorded for all previously uninfected contacts who had TST indurations  $< 5$  mm or negative IGRA results and no TB symptoms during the first screening. This group of contacts should have the following:

- TB sign/symptom screen
- IGRA or TST

## Contact Investigations, cont'd

Window-period screenings must be recorded on the “TB Contact Investigation Line List” and in the EHRS TB Testing Evaluation Report (TB Evaluation and Testing section). When the window-period screenings are completed, the PHN will present the automatically calculated summary data to the CI team. The CI team will determine whether or not disease transmission has occurred and if the CI should be expanded. The LHD health officer or TB Controller and CME may terminate the CI when there is no further evidence of ongoing disease transmission.

### Step 9: Paroled, Released or Discharged Patient Contacts

Within two business days, the “Transferee Follow-Up Request Form” or the “TB Contact Letter for Institutions form” (either form can be used) should be completed for all identified high priority contacts who are no longer housed in the originating institution. The PHN will create separate lists for the following, but all final results need to be entered into the main “Contact Line List” tab to make sure the data is captured as part of the summary data.

- For patient contacts transferred within CDCR facilities and identified to be high priority, the PHN will email (*with ‘High Importance!’*) the list of high priority transferees to the following:
  - CME where the contact is currently housed
  - PHN or designee where the contact is currently housed
  - CCHCS Public Health Nurse Consultant Program Review (NCPR)
- The PHN will request that transferee screening results be sent (*with ‘High Importance!’*) within 10 business days to the originating institution PHN and CCHCS PH. If the originating institution PHN does not receive the transferee screening results within 10 business days, their designated CCHCS PH nurse consultant can be contacted to assist in obtaining the information.
- For patient contacts who were paroled, released, or discharged to the community and are now identified to be high priority, the PHN will email the parolee/released/discharge list (*including [encrypt] in the subject line*) to the originating institution’s LHD and copy CCHCS NCPR.
  - PHN to request that the LHD will send the community CI results to the requesting PHN. The results must be included in the final CI summary. If the community contact screening information is not received from the LHD within 30 business days, the originating institution PHN will follow-up with the LHD to request the results. If within 30 business days, the LHD cannot provide information on community contacts, the LHD will determine and notify the institution PHN if more time is needed to locate community contacts or if the community contacts are lost to follow up.
  - Both the results of the transferees and community contacts results must be entered in the main “Contact Line List” tab on the “TB CI Line List” for the information to include as part of the final CI summary report.

### Step 10: Final Reporting and Contact Investigation Team Teleconference

The institution PHN, in consultation and review with CCHCS PH (physician lead and nurse consultant) will provide the “TB Contact Investigation Summary page”, that is automatically generated from the “TB Contact Line List” to the CI team members in the institution, LHD, and CCHCS PH.

## Contact Investigations, cont'd

During the final CI team teleconference, the completed patient CI findings will be presented. The employee CI findings will be presented by the EHP representative. Based on the rate and number of patient and employee baseline and/or new infections, the CI team will determine if the CI should be expanded or terminated. The LHD TB Controller/Health Officer and CME may terminate the CI when there is no further evidence of ongoing disease transmission.

Note: When there is documented transmission of TB, the CI may quickly expand to add more contacts to the high priority group.

### Complete and Report Final Summaries of Screening and TB Treatment Results

Within 10 business days of the close of the TB CI, and again 30 business days after completion of LTBI treatment for the new positives, the final "TB Contact Investigation Summary page" must be sent to the originating institution's CME for review and signature.

After signed approval:

- 1) The TB CI summary page can be released to the institution's Warden, CEO, CME, CNE and PHN; &
- 2) The TB CI summary page plus the final CFTP can be released to the LHD and CCHCS PH.

## Step 11: Archiving Documentation for Future Reference

Months or years after a TB CI, the results of the CI may be reviewed, e.g., requested by legal authorities. Both the originating institution and CCHCS PH must keep a copy of the following documents (preferably as electronic files on a shared drive):

- 1) All detailed meeting minutes and other documents pertaining to the CI
- 2) Completed TB patient interview form
- 3) The TB Contact Investigation Line List (this includes the index case information)
- 4) The TB CI Summary page (separately saved) since it contains the institution's CME's signature
- 5) The final CFTP

**Section VII Table 1. Contact Investigation Requirements in California State Prisons**

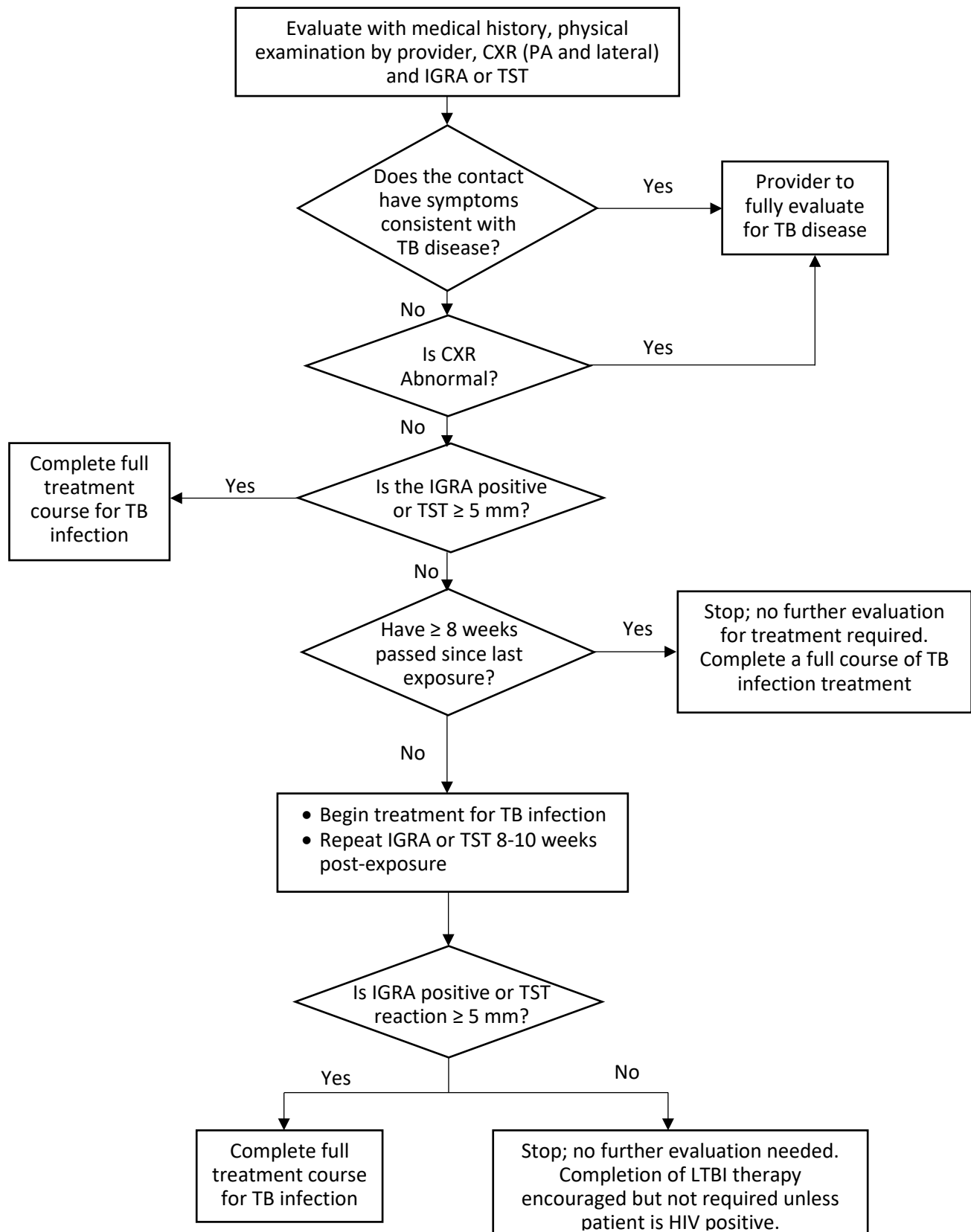
Adapted from “Guidelines for Coordination of TB Prevention and Control by Local and State Health Departments and California Correctional Health Care Services 2015”

TB Classification	Index Case Characteristics	Decision to initiate a contact investigation	Minimal recommendation for beginning of the likely period of infectiousness	Business days from listing of a contact to initial encounter*	Business days from initial encounter to complete medical evaluation*
<b>TB 3</b> Culture – confirmed TB from a respiratory specimen (sputum, bronchial fluid, laryngeal, or identified lung tissue biopsy)	1. Patient with at least <u>one</u> of the following: A. Positive AFB smear on a respiratory specimen, or NAAT positive; B. Cavitory CXR; or C. TB symptoms.	Always consult with your local health department	3 months prior to symptom onset or first positive findings (e.g., abnormal chest radiograph) consistent with TB disease, whichever is longer	High priority contact 3-5 days	High priority contact 5 days
	2. Patient with <u>all</u> of the following: A. Negative AFB smears; and B. No cavitory lesions on CXR; and C. No TB symptoms.	Always consult with your local health department	4 weeks prior to date of diagnosis as a confirmed case	High priority contact 7 days	High priority contact 10 days
<b>TB 5</b> High suspicion (culture pending) from a respiratory specimen, started on presumptive treatment for active TB disease	1. Patient with at least <u>one</u> of the following: A. Positive AFB smear on a respiratory specimen <b>and</b> NAAT positive or NAAT not done; or B. 3 negative AFB smears and 1 NAAT positive on a respiratory specimen.	Always consult with your local health department	3 months prior to symptom onset or first positive findings (e.g., abnormal chest radiograph) consistent with TB disease, whichever is longer	High priority contact 3-5 days	High priority contact 5 days
	2. Patient with <u>all</u> of the following: A. Three negative AFB smears; and B. 1 NAAT negative on a respiratory specimen; and C. No cavities on CXR; and D. No respiratory signs or symptoms.	Consult with local health department to determine if a contact investigation is recommended	4 weeks prior to date of diagnosis as a confirmed case	High priority contact 7 days	High priority contact 10 days

Section VII Table 1. Contact Investigation Requirements in California State Prisons, Cont'd

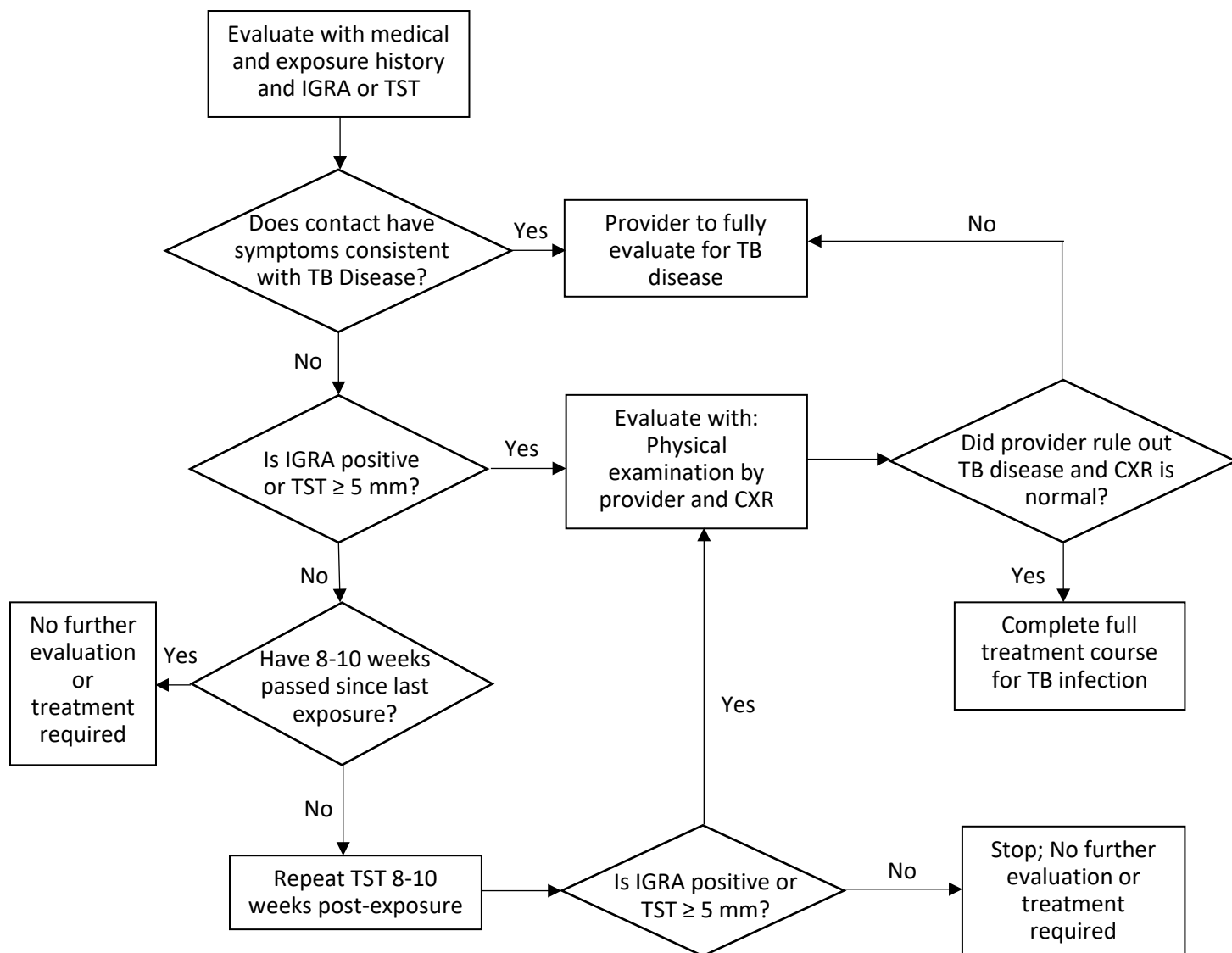
TB Classification	Index Case Characteristics	Decision to initiate a contact investigation	Minimal recommendation for beginning of the likely period of infectiousness	Business days from listing of a contact to initial encounter*	Business days from initial encounter to complete medical evaluation*
TB 5 Low suspicion (culture pending) from a respiratory specimen, not started on presumptive treatment for active TB disease	1. Patient must have all of the following: A. Three negative AFB smears; and B. 1 negative NAAT; and C. No cavities on CXR; and D. Most recent HIV test is negative <b>and</b> was taken in the past 6 months; and E. No respiratory signs or symptoms.	A contact investigation is not indicated. If respiratory specimens are subsequently culture positive for Mycobacterium TB, follow guidelines for TB 3.			
Extrapulmonary TB	No pulmonary, laryngeal, or pleural involvement	Not applicable			
<p>*These are time-frames for initial follow-up of persons exposed to tuberculosis. Comments on prioritizing high priority contacts:</p> <ul style="list-style-type: none"><li>Symptomatic contacts need immediate referral and evaluation, regardless of type of contact or index case characteristics.</li></ul> <p>High priority contacts at highest risk for progression from TB infection to disease or increased severity of TB disease should be evaluated as quickly as possible.</p>					

## Section VII Flowchart 1. Immunocompromised Contact



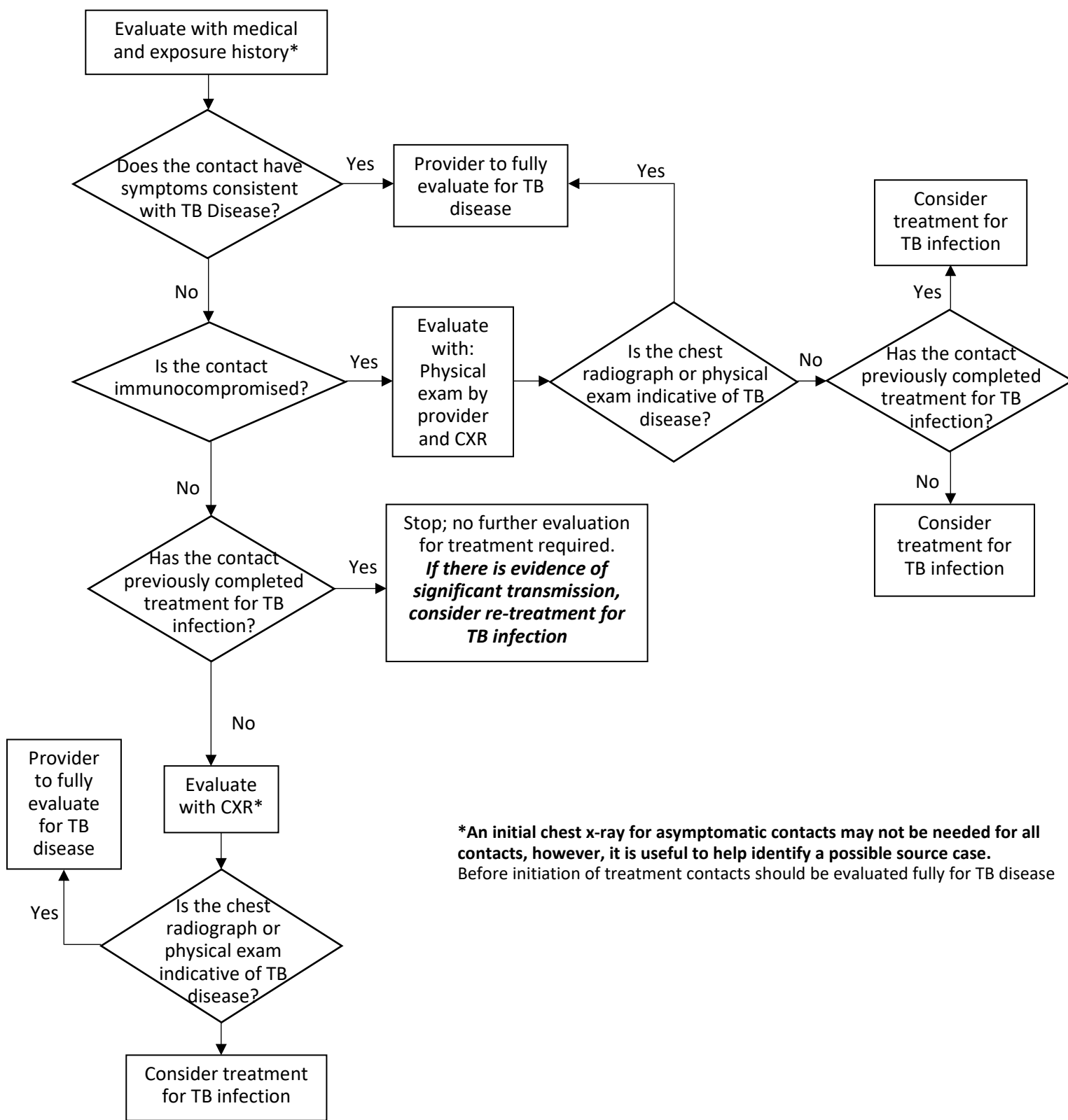


## Section VII Flowchart 2. Immunocompetent Contact



Adapted from: CDPH/CTCA Joint Addenda. California Department of Public Health and California Tuberculosis Controllers Association. Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis. Addendum 32. Page 44. Accessed 5/19/23

### Section VII Flowchart 3. Prior IGRA or TST Positive Contact



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## Appendix A. Reporting of Suspected and Confirmed (Active) Tuberculosis Patients

For patients with suspected active TB disease, providers should notify the institution Public Health Nurse and leadership, and ensure immediate reporting to the CCHCS PH and the LHD. CCHCS PH may be notified via the warmline phone (916-691-9901) and email ([CDRCRPHCSPublicHealth@cdcr.ca.gov](mailto:CDRCRPHCSPublicHealth@cdcr.ca.gov)) as per HCDOM 3.8.1 Public Health Disease Reporting, and HCDOM 3.8.6 Tuberculosis Program.

All suspect cases of tuberculosis disease are reportable to the LHD per Title 17 of the California Code of Regulations within one working day.

The Correctional Facility Tuberculosis Patient Plan (CFTP) must be completed for each patient suspected of active TB disease. The initial CFTP should be submitted to both the LHD and CCHCS PH within 24 hours by the institution PHN. Additional CFTP updates are submitted by the institution PHN to CCHCS PH and the LHD of the institution in each of the following circumstances:

- Patient started on TB treatment. TB medication regimen is changed, discontinued, or completed.
- Lab test results available: including nucleic acid amplification tests (NAATs) or acid-fast bacilli (AFB) smear, AFB culture, or HIV results.
- *M. tuberculosis* drug sensitivity results returned.
- Patient is transferred to a contract hospital or another institution.
- Patient is paroled or discharged.
- Immediately to the receiving institution when the patient is transferred to another institution.
- To the LHD of the jurisdiction where the patient was incarcerated and the LHD of the receiving jurisdiction when a patient is paroled or discharged.

## Appendix B. Infection Control

The most important infection control procedures for patients with confirmed or suspected TB disease is appropriate use of isolation, including use of an airborne infection isolation room (AIIR).

### Airborne Infection Isolation Room (AIIR)

AIIR's located within CDCR facilities should be appropriately certified and checked regularly to ensure negative pressure is adequate before and during occupancy. One way to test for negative pressure is to hold a single-ply tissue at the bottom of the door or other small opening into the room. If the tissue is drawn into the room the pressure is negative.

### Personal Protective Equipment (PPE)

Any staff within the shared airspace of the patient should don an N95 or other NIOSH approved respirator. Staff should have been appropriately trained and fit-tested for the model or brand of respirator to be utilized prior to having encounters with suspect or confirmed TB cases.

### Cleaning and Disinfection

**Routine Cleaning:** Any room housing suspected or confirmed TB cases should be cleaned and disinfected as per routine practices while the room is occupied. Surfaces or equipment that are most likely to be contaminated with blood or body fluids should be cleaned using an EPA registered disinfectant with tuberculocidal activity. Any staff entering the room to perform general cleaning and disinfection should wear appropriate respiratory protection devices as noted above.

**Terminal Cleaning:** Once a patient vacates a room staff should wait for the ventilation and/or filtration system to clear the air of TB aerosols before entering the room without wearing a respirator or assigning the room to a new patient. Once the air is appropriately scrubbed of TB Aerosols the room can be cleaned and disinfected following standard terminal cleaning practices.

- The clearance time for AIIRs can range from 30 minutes to 2 hours depending on the ventilation system employed. All doors to the room should remain closed to allow the ventilation system to clear the air and respiratory protection should be utilized if room entry is required within that timeframe. Each institution should verify the clearance time for their installed systems.
- For non-negative pressure (recirculated air) rooms in which a suspect or confirmed patient is temporarily housed while unmasked (Clinic, TTA, etc.) a portable HEPA filter can be employed to help clear TB aerosols. The unit should run for a minimum of 30 minutes (or one hour if the room is large). If no HEPA filter is employed the room should not be occupied for one hour. Room entry should be avoided but if entry is necessary, Respiratory Protection should be utilized for room entry at any time during that time period.

### Laundry

Laundry should be handled as little as possible avoiding contact with one's body and personal clothing. Do not shake or handle items in such a manner that they may aerosolize infectious particles. Soiled laundry should be collected at bedside and contained within a dissolvable bag and then placed in a yellow bag prior to sending to the laundry facility.

## Appendix C. Tuberculosis Medications

MEDICATION	Dose	Contraindications	ADVERSE EFFECTS/ INTERACTIONS*	COMMENTS
<b>Isoniazid (INH)</b>  Tablet: 100 mg, 300 mg  \$	LTBI treatment 3HP: 15 mg/kg weekly 3HR: 5 mg/kg daily 6H, 9H= 15 mg/kg twice weekly Active TB disease 5 mg/kg daily  INH max dose:  5mg/kg = 300mg/dose  15mg/kg = 900mg/dose	<b>Black Box Warning:</b> May cause serious or fatal hepatitis. Risk of developing hepatitis is age-related and may occur many months after treatment though usually within the first 3 months of therapy  <b>Contraindications:</b> hypersensitivity to INH or any component including drug induced hepatitis; acute liver disease; previous history of hepatic injury with isoniazid therapy; previous severe adverse reaction to isoniazid	<b>Adverse effects Serious:</b> Hepatotoxicity (0.1%), agranulocytosis, aplastic anemia, thrombocytopenia, optic neuritis, peripheral neuropathy (0.2%), toxic psychosis, seizures, pancreatitis, DRESS  <b>More common adverse events:</b> paresthesia, nausea, vomiting, epigastric discomfort, elevated ALT, AST (10-20%), hypersensitivity reactions, pyridoxine deficiency  Caution in patients with renal impairment <b>Drug interactions:</b> <ul style="list-style-type: none"> <li>• Increase the serum levels of alprazolam, dofetilide, and disulfiram</li> <li>• Other interactions (not exhaustive) acetaminophen, corticosteroids, cycloserine, cyclosporine, dolutegravir, carbamazepine, fosphenytoin-phenytoin, itraconazole, ketoconazole, levodopa-foslevodopa, midazolam, simvastatin, sirolimus, theophylline, warfarin</li> </ul>	<ul style="list-style-type: none"> <li>• Administer with pyridoxine 50 mg/day to prevent neuropathy</li> </ul>
<b>Ethambutol (EMB)</b>  Myambutol® Tablet: 400 mg  \$\$	40-55 kg: 14.5-20 mg/kg once daily (max: 800 mg/day)  56-75 kg: 16-21.4mg/kg once daily (max: 1200 mg/day)  76-90 kg: 17.8-21.1 mg/kg once daily (max: 1600 mg/day)  <u>Renal impairment:</u>  CrCl<30 ml/min or hemodialysis: 15-25 mg/kg per dose three times per week (not daily)	<b>Contraindications:</b> hypersensitivity to ethambutol or any component of the formulation, optic neuritis, patients unable to report visual side effects or changes in vision  Caution in patients with renal impairment	<b>Adverse effects:</b> optic neuritis, skin rash, nausea, vomiting, hyperuricemia <b>Drug interactions:</b> aluminum containing antacids  Avoid concurrent administration of ethambutol with aluminum hydroxide containing antacids for at least 4 hours following ethambutol administration	<ul style="list-style-type: none"> <li>• Optic neuritis is very rare at 15 mg/kg if kidney function is normal and is reversible with discontinuation of medication</li> </ul>

**Bold = Formulary**

\*Prior to starting therapy, consult detailed prescribing information to review all potential drug-drug interactions, contraindications, and other precautions.

The cost scale \$-\$\$\$\$\$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.

MEDICATION	Dose	Contraindications	ADVERSE EFFECTS/ INTERACTIONS*	COMMENTS
<b>Pyrazinamide (PZA)</b>  Tablet: 500 mg  \$\$\$	<u>40-55 kg:</u> 18.2-25 mg/kg once daily (max: 1000 mg/day) <u>56-75 kg:</u> 20-26.8 mg/kg once daily (max: 1500 mg/day) <u>76-90 kg:</u> 22.2-26.3 mg/kg once daily (max: 2000 mg/day) <u>Renal impairment:</u> CrCl<30 ml/min or hemodialysis: 25-35 mg/kg per dose three times per week (not daily)	<b>Contraindications:</b> patients with severe hepatic damage or acute gout or with prior hypersensitivity  Caution in patients with diabetes or liver disease	<b>Adverse effects:</b> hepatotoxicity, nausea, vomiting, anorexia, jaundice, abnormal LFTs, polyarthralgia, hyperuricemia, gout (rare), rash  <b>Drug interactions (not exhaustive)</b> Cyclosporine	<ul style="list-style-type: none"> <li>Generally not used in pregnancy</li> </ul>
<b>Rifampin (RIF)</b>  Rifadin® Capsule:  150 mg, 300 mg  \$	<u>Once daily:</u>  10 mg/kg (max: 600 mg/dose)	<b>Contraindications:</b> hypersensitivity to rifampin, or any patients receiving atazanavir, darunavir, fosamprenavir, lurasidone, ritonavir/saquinavir, or saquinavir, or tipranavir, or praziquantel	<b>Serious Adverse effects:</b> hepatitis (0.6%), thrombocytopenia, leukopenia, hemolytic anemia, agranulocytosis, hemorrhage, DIC, interstitial nephritis, renal failure, anaphylactic shock, psychosis, porphyria exacerbation, erythema multiforme, Stevens-Johnson syndrome, Toxic epidermal necrolysis, C. difficile-assoc. diarrhea, hepatotoxicity  <b>Common adverse events:</b> anorexia, nausea/vomiting, headache, elevated ALT, AST, fatigue, drowsiness, dizziness, abdominal pain, diarrhea, hypersensitivity reaction, influenza-like symptoms, dyspnea, ataxia, vision changes, contact lens staining. May increase risk of sunburn.  <b>Drug interactions:</b> Many. <ul style="list-style-type: none"> <li>Decreases blood levels of oral contraceptives, warfarin, sulfonylureas, methadone, steroids, and some antibiotics including fluoroquinolones.</li> <li>Acetaminophen, amiodarone, amitriptyline, amlodipine, atorvastatin, betamethasone, brincidofovir, buprenorphine, carvedilol, clozapine, digoxin, diltiazem, Fluvastatin, etc.</li> <li>Has interactions similar to rifapentine; induces cytochromes P4503A4 &amp; P4502C8/9.</li> <li>HC treatments</li> </ul>	<ul style="list-style-type: none"> <li>Caution in patients with diabetes or liver dysfunction; concomitant use with etravirine, nevirapine, or any protease inhibitor</li> <li>Orange urine, sweat, saliva or tears may permanently stain dentures and contact lenses</li> </ul>

**Bold = Formulary**

\*Prior to starting therapy, consult detailed prescribing information to review all potential drug-drug interactions, contraindications, and other precautions. The cost scale \$-\$\$\$\$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.



MEDICATION	Dose	Contraindications	ADVERSE EFFECTS/ INTERACTIONS*	COMMENTS
Rifabutin (RBT)  Mycobutin® Capsule: 150 mg \$\$\$\$	<u>Once daily:</u>  5 mg/kg (max: 300 mg/dose)  <u>Renal impairment:</u>  CrCl<30 ml/min: reduce dose by 50%	<b>Contraindications:</b> Clinically significant hypersensitivity to rifabutin or other rifamycins or any component of the formulation	<b>Adverse effects:</b> neutropenia, uveitis, polyarthralgias, hepatotoxicity, rash including Stevens-Johnson and toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), orange discoloration of body fluids, nausea, vomiting.  <b>Drug interactions (not exhaustive):</b> Alprazolam, amlodipine, aripiprazole, buprenorphine, cabotegravir, carbamazepine, cyclosporine, darunavir, diltiazem, dolutegravir, nifedipine, sertraline, simvastatin, HCV treatments	<ul style="list-style-type: none"> <li>• Caution in patients with neutropenia or thrombocytopenia</li> <li>• Orange urine, sweat, saliva or tears may permanently stain dentures and contact lenses.</li> <li>• Weaker inducer of hepatic microsomal enzymes than rifampin</li> <li>• Fewer drug interactions with HIV meds than rifampin</li> </ul>
<b>Rifapentine</b>  (RPT)  Priftin®  Tablet: 150 mg \$\$\$\$	32.1–49.9 kg 750 mg weekly  ≥50 kg 900 mg (max) (Six 150 mg tabs)  NOTE: Rifapentine is formulated as 150 mg tablets	<b>Contraindications</b> HIV infection on ART, pregnancy, hypersensitivity to rifamycins (rifampin, rifabutin), Exposure to rifampin-resistant MTB	<ul style="list-style-type: none"> <li>• <b>Serious adverse events:</b> neutropenia, leukopenia, thrombocytopenia, hepatotoxicity (0.6%), interstitial nephritis, hypersensitivity reaction, anaphylaxis, pancreatitis, porphyria exacerbation, C. difficile-assoc. diarrhea</li> <li>• <b>Common adverse events:</b> reddish-orange body fluids, elevated ALT, AST, hyperbilirubinemia, neutropenia, pyuria, proteinuria, hematuria, lymphopenia, urinary casts, rash, pruritus, acne, anorexia anemia, leukopenia, arthralgia, pain, nausea, vomiting, contact lens staining.</li> <li>• <b>Drug interactions (not exhaustive)</b> Decreases blood levels of oral contraceptives, warfarin, sulfonylureas, methadone, steroids, and some antibiotics including fluoroquinolones. Induces cytochromes P4503A4 &amp; P4502C8/9 (less than rifampin). Antiepileptic drug therapy Calcium channel blockers Sulfonylureas (oral hypoglycemics) Clarithromycin/erythromycin; Azole antifungals; HIV antiretroviral therapy; Hepatitis C treatment; Anti-rejection medications</li> </ul>	<ul style="list-style-type: none"> <li>• Orange urine, sweat, saliva or tears may permanently stain dentures and contact lenses.</li> </ul>

**Bold = Formulary**

\*Prior to starting therapy, consult detailed prescribing information to review all potential drug-drug interactions, contraindications, and other precautions.

The cost scale \$-\$\$\$\$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.

## Appendix D. Community Hospital Communications

**TO COMMUNITY HOSPITAL STAFF**

A TB suspect inmate-patient has been transferred to your facility from the California Correctional Health Care Services (CCHCS) of the California Department of Corrections and Rehabilitation (CDCR) for respiratory isolation and evaluation.

This handout will assist you in evaluation of our patient by outlining the very specific requirements of the CCHCS TB suspect evaluation protocol arising from our high risk setting for TB transmission.

**Please see below for the following requirements:**

- Respiratory specimen collection and other evaluation
- Return to a CDCR institution

**CCHCS TB RESPIRATORY SPECIMEN COLLECTION PROTOCOL**

1. Collect respiratory specimens for all patients in whom pulmonary, pleural, or laryngeal TB is suspected, as well as in those in whom extrapulmonary TB has been diagnosed.
2. Specimen collection must be performed with the patient isolated in an AIIR.
3. **All** of the following are required for a complete initial laboratory evaluation of respiratory specimens for both low and high suspect TB patients:
  - **Collection of three respirator specimens** according to this protocol:
  - **AFB smear on all three specimens**
  - **AFB culture of all three specimens**
  - Specimens must be collected **at least 8 hours apart**
  - One of the specimens must be collected:
    - in the early morning (preferred), or
    - by sputum induction (second choice), or
    - by bronchoalveolar lavage (BAL) (last choice).
  - Performance of nucleic acid amplification testing (NAAT) on **at least one** of the respiratory specimens
    - The NAAT test should be performed on an AFB positive smear, if available.
    - One of the specimens must be tested by NAAT even if all smears are AFB negative.
    - If all AFB smears are negative, any of the specimens may be chosen for NAAT testing, however, it is preferable to test the specimen that was collected in the early morning, by sputum induction, or by BAL.

**OTHER EVALUATION:** If HIV status is unknown, an HIV test **MUST** also be performed.

**Please contact our institution if you have questions:** \_\_\_\_\_

**Medical Department Telephone#** \_\_\_\_\_  
(24-hour contact number)

**SEE NEXT PAGE FOR INSTRUCTIONS ON RELEASE FROM HOSPITAL AND RETURN TO  
STATE CORRECTIONAL FACILITY**



## TO COMMUNITY HOSPITAL STAFF

### INSTRUCTIONS FOR RELEASE FROM HOSPITAL AND RETURN TO STATE CORRECTIONAL FACILITY

**LOW SUSPECT TB CASES**- Patients worked up for TB but not placed on rifampin, isoniazid, pyrazinamide, ethambutol (RIPE) treatment.

Work-up must be reviewed by the accepting institution's Chief Medical Executive or designee.

- ❖ Patients not on TB treatment are usually accepted for return to the institution **when** all the following criteria have
  - 1) HIV negative test in past 6 months,
  - 2) All respiratory specimens collected correctly (including timing and types of specimens) and sent for smear **and** culture,
  - 3) All smears negative for AFB AND all NAATs negative for MTB (or AFB smear positive and NAAT negative for MTB),
  - 4) The patient has **no** cough,
  - 5) The CXR does **not** show a cavitory lesion (note: a CT scan may have a cavitory lesion).
- ❖ Low suspect TB cases who do not meet the 5 criteria above must be reviewed by the local TB controller and the CME (or designee) of the accepting institution before release from the community hospital.
  - Low suspect patients who are smear positive for AFB but NAAT negative for MTB can usually be returned to the institution if the other criteria for return of a low suspect patient are met (see above). Occasionally these patients will need review by the local TB controller prior to returning to the institution.

**HIGH SUSPECT TB CASES** - Patients placed on RIPE treatment

- ❖ High suspect patients **with THREE smears negative for AFB** (even if the NAAT is positive for MTB) may return to
  - After the patient has taken and tolerated **five days** of RIPE, **and**
  - The local TB controller has approved of a written treatment plan for the patient (required by law), **and**
  - The CME (or designee) has approved the transfer.
- ❖ High suspect TB cases **with any AFB smear positive for AFB** (unless the AFB smear is NAAT negative for MTB) may be released from AIIR:
  - After the patient has taken and tolerated **14 days** of RIPE, **and**
  - Subsequent smear results are AFB negative, **and**
  - Patient is clinically improved, **and**
  - The local TB controller has approved of a written plan for the patient (required by law), **and**
  - The CME (or designee) has approved the transfer.

*Note: High suspect TB patients generally remain on RIPE until their cultures return when a decision is made about continuing/not continuing the course of treatment (e.g., if the cultures are negative and there is no clinical indication that the patient has TB disease). Some patients may have RIPE discontinued prior to culture return **if** the local TB controller has approved of that plan.*

## Appendix E. Tuberculosis Definitions

**Category S Patients:** Category S patients are patients that are transferred into CDCR facilities from city or county jails because of earthquakes, riots, etc.

**Confirmed TB (Laboratory):** Confirmed TB disease that is confirmed by the presence of *M. tuberculosis* complex (MTB) bacteria on culture. Culture remains the gold standard for laboratory confirmation of TB disease. Culture examinations must be performed on all diagnostic specimens, regardless of AFB smear or NAAT results as MTB complex bacteria may grow in culture specimens that were AFB smear and NAAT negative.

**Clinically Confirmed TB:** In the absence of a positive culture, TB disease may be diagnosed based on the clinical signs and symptoms. The diagnosis may also be based on clinical response to TB treatment.

**Close Contact:** A person who had prolonged, frequent, or intense contact with a person with TB while he/she was infectious. Close contacts are more likely to become infected with *M. tuberculosis* than contacts who see the patient less often.

**Concentric Circle:** A method of screening and testing contacts in order of intensity of exposure (close vs. other-than-close) and risk of becoming infectious (high priority vs. low priority). Close contacts and high priority contacts at high risk of developing TB disease are screened and tested first.

**Contacts:** Individuals sharing air space with a patient identified with infectious TB disease during their likely period of infectiousness.

**Contact Investigation (CI):** A procedure for identifying people exposed to someone with infectious TB, evaluating them for LTBI and TB disease, and providing appropriate treatment for TB infection and TB disease.

**Exposure:** The significance of an exposure depends on the infectiousness of the TB patient and strain, duration, characteristics of the location of contact with a patient with TB disease, and immunosuppression of the contact.

**Exposure Period:** Range of time in which a contact was exposed to a patient with TB disease during the infectious period.

**Extrapulmonary TB:** TB disease that occurs outside of lungs.

**High Priority Contacts:** Contacts with either:

- Close and/or high intensity exposure (as defined by the CI team based on length, ventilation, coughing, and location of contact), or
- Immunosuppression. The following medical conditions can cause the contact to be at particularly high risk of developing TB disease if they become infected with *M. tuberculosis*:
  - HIV-infected
  - Had organ transplant and is on transplant immunosuppression
  - Otherwise immunosuppressed (e.g., receiving TNF-alpha antagonists or the equivalent of 15 mg/day of prednisone for  $\geq$  one month
  - Chemotherapy for cancer or TNF-alpha antagonists

## APPENDIX E: TUBERCULOSIS DEFINITIONS, cont'd

**High Risk Condition:** High risk of developing TB disease. Persons with high-risk conditions include:

- Recent contact with a person with active TB (all contacts in a contact investigation).
- Abnormalities on a chest x-ray (CXR) consistent with old TB disease.
- HIV-infected or has an unknown HIV infection status.
- Has had an organ transplant and is on transplant immunosuppression, or is otherwise immunosuppressed (e.g., receiving the equivalent of  $\geq 15$  mg/day of prednisone for  $\geq$  one month, chemotherapy for cancer, or tumor necrosis factor [TNF]-alpha antagonists).
- End stage renal disease on hemodialysis.
- Diabetes (moderate risk).

**High Suspect TB:** are patients with signs and symptoms that are so highly characteristic or suspicious for TB disease that treatment is warranted pending confirmation.

**Infectious Period:** Typically starts 12 weeks before the patient was diagnosed with TB or before symptom onset (one month if asymptomatic) and extends until the infectious individual has been removed from the general population and isolated. The infectious period is variable and depends on the clinical characteristics of the TB patient.

**Interferon Gamma Release Assay (IGRA) Tests:** Laboratory assays that measures reaction to TB antigen. Positive assays indicate prior infection. e.g., QuantiFERON TB Gold In-tube test and T-Spot. Are considered more specific for TB than TST's and thus less likely to cause false positive reaction after infection with non-TB (atypical) mycobacteria or after sensitization with Bacillus Calmette-Guérin (BCG) vaccination. They should not be used as a confirmatory test for TST positives and if a patient refuses an IGRA, a TST may be used.

**Latent TB Infection (or TB Infection):** Patients who are infected with *M. tuberculosis* complex bacteria; patients with Latent TB Infection (also known as TB infection) are not contagious. Persons with LTBI carry the organism that causes TB but do not have TB disease, are asymptomatic, and are noninfectious. Persons with TB infection usually have a positive reaction to the tuberculin skin test or IGRA.

**Line List:** A spreadsheet tool designed to assist contact investigators in keeping a list of those who may have been exposed to an infectious case of TB (Not a replacement for other required medical or nursing documentation).

**Low Suspect TB:** Clinical suspicion for TB disease that is not high enough to warrant TB treatment.

**Multidrug Resistant TB:** TB caused by an organism that is resistant to (at least) both isoniazid (INH) and rifampin (RIF).

**New TB Infection:** In a CI, defined as a new tuberculin/TB skin test (TST) reading  $\geq 5$  mm or a newly positive TB blood test (IGRA) and with no TB sign/symptoms and negative CXR. If the baseline TST is  $> 0$  mm and  $< 10$  mm, then an increase of 5 mm is a new infection.

**Open-Ended Questions:** Questions that cannot be answered with a simple "yes" or "no." They are designed to elicit the patient's knowledge, feelings, and beliefs by beginning with words such as "What," "Why," "Who," "How," and "When," that demand an explanation. They are used to explore complex issues that do not have a finite or predetermined set of responses.

**Other-Than-Close Contacts:** Contacts with less intense, less frequent, or shorter duration of contact to the TB patient than close contacts.

**Positive TST:** Induration of  $\geq 5$  mm for patients with a high-risk condition. Induration of  $\geq 10$  mm for all others.

**Pulmonary TB:** TB disease confined to lungs.

## APPENDIX E: TUBERCULOSIS DEFINITIONS, cont'd

**Recent TB infection:** TB infection occurring in the past 2 years. Known recent exposure to a TB case and a positive IGRA test or a new  $\geq 5$  mm TST (these patients are most often identified during a contact investigation), or patients with a positive IGRA test or a positive TST on arrival at reception ( $\geq 5$  mm induration with a high-risk condition [e.g., immunocompromised] or  $\geq 10$  mm induration without a high-risk condition).

**Remote TB infection:** Documented TB infection more than 2 years prior.

**Significant Exposure:** An exposure to a TB case in which the circumstances of the exposure make TB transmission sufficiently likely that the contact requires inclusion in a line list and further evaluation by a health care provider.

**Source Patient/Case:** Person with infectious TB disease who is responsible for transmitting *M. tuberculosis* to another person or persons. He/she is identified through either a contact or source case investigation and may or may not be the TB case patient (see TB case patient).

**Symptom screening:** Patients are asked about cough more than 3 weeks, fever, weight loss, night sweats, or hemoptysis. If any positive, they are referred for assessment.

**TB Disease:** Clinical evidence of active TB disease.

**TB Case Patient:** A person with suspected or confirmed TB disease who is the initial case reported to the health department. The index case may or may not be the source case (see source case).

**TB Infection (Latent TB Infection):** Patients who are infected with *M. tuberculosis* complex bacteria; patients with TB infection (also known as Latent TB Infection) are not contagious. Persons with TB infection carry the organism that causes TB but do not have TB disease, are asymptomatic, and are noninfectious. Persons with TB infection usually have a positive reaction to the tuberculin skin test or IGRA.

**TB Treatment Completion:** Ingestion of the prescribed number of TB medication doses within a specified timeframe.

**TB Treatment Team:** TB treatment in CCHCS is always managed by a TB Treatment Team of physicians, nurses, and public health practitioners headed by the CME of the patient's institution under the legally mandated oversight of the LHD TBC.

**Tuberculin Skin Test (TST):** Alternative method in CCHCS for detection of exposure and infection to TB. Antigen injected in skin and induration measured. Recorded in millimeters (mm) of induration (raised, hardened area or swelling). Do not measure erythema. Interpreted as "positive" or "negative" dependent on clinical factors or known exposure to TB. The indurated area should be measured across the forearm (perpendicular to the long axis of the arm). Those with documented severe necrotic reaction to the TST should have an interferon gamma release assay (IGRA) test instead of TST. Pregnancy, lactation, or previous BCG vaccinations are not contraindications for a TST.

**Tuberculin Skin Test Conversion (TST):** Defined differently from a standard skin test conversion; for contacts, a skin test conversion is defined as a change from  $< 5$  mm on the initial skin test to a reaction of  $\geq 5$  mm on the second test, 10 to 12 weeks after exposure.

**TNF-alpha antagonist:** Tumor necrosis factor (TNF) alpha antagonists are a class of drugs that inhibit TNF-alpha and are used in the treatment of several autoimmune and other diseases. These drugs affect the immune system and predispose individuals to infections, including mycobacterial infections such as tuberculosis. Drugs in this class include: etanercept, infliximab, and adalimumab, etc.

**Window Period:** Time span between the date of an initial TB skin test with a negative reaction and the date of the follow-up TB skin test that should take place 10 – 12 weeks after exposure. After the window period has ended, a repeat skin test should be administered to each contact who had an initial negative reaction.

**Window Period Prophylaxis:** The practice of providing treatment for LTBI to high-risk contacts (including HIV infected and other immunosuppressed persons) with an initial negative skin test reaction less than 10 to 12 weeks after their exposure. If the contact has a negative skin test reaction after the window period, treatment for TB infection is usually stopped.

## PATIENT EDUCATION

### LATENT TUBERCULOSIS INFECTION: WHAT YOU SHOULD KNOW

#### WHAT IS LATENT TUBERCULOSIS INFECTION?

Latent tuberculosis (TB) infection is an infection caused by TB bacteria or germs that are spread from person to person through the air. If you have spent time close to someone with active TB disease you could have breathed TB bacteria into your lungs.

If you have spent time with someone who has active TB disease, you should talk to your health care team about being tested for TB.

Someone with latent TB infection cannot spread the bacteria to other people. If you have spent time with someone with latent TB infection, you do not need to be tested for TB.



#### WHAT ARE THE SYMPTOMS OF LATENT TB INFECTION?

If you have latent TB infection, the TB bacteria are alive in your body, but they are not hurting you now.

There are no symptoms when you have latent TB infection. The TB bacteria are asleep in your body, but they could start to grow and spread. When the bacteria grow and spread it is called active TB disease. People with active TB disease can get very sick and can spread TB to other people.

**This can happen to anyone with latent TB infection at any time, however, there are medications you can take to prevent you from becoming sick in the future.**

#### HOW DO I KNOW IF I HAVE TB INFECTION?

A TB blood test or a TB skin test will show if you have TB infection.

If you are told your TB test is positive you will get:

1. A chest x-ray (CXR) to see if you have TB disease in your lungs.
2. A physical exam to make sure you don't have TB disease in other parts of your body.

If your health care provider tells you that your CXR is normal and you have no symptoms of active TB disease in your body, you will be told that you have TB infection.

See pages PE-9 and PE-10 for information on TB testing.

#### IS EVERY PERSON WITH LATENT TB INFECTION AT RISK OF GETTING ACTIVE TB DISEASE?

All people with latent TB infection are at risk for the TB bacteria to spread and grow into TB disease. The risk of getting TB disease is even higher in the first two years after you get TB infection. Some people have conditions that cause them to be at even higher risk for this to happen. Talk with your health care provider if you have:

- HIV infection
- Other health problems, like diabetes
- Alcohol abuse or illegal drug use
- Taken TB infection medicine before, but did not complete treatment



## PATIENT EDUCATION

### LATENT TUBERCULOSIS INFECTION: WHAT YOU SHOULD KNOW, Continued

#### IF I HAVE LATENT TB INFECTION, HOW CAN I PREVENT ACTIVE TB DISEASE?

If you have latent TB infection, there are medicines to take for preventing you from getting TB disease. The TB infection medicines destroy the sleeping TB bacteria before they have a chance to make you sick.

Your health care provider will order TB infection medicine that is best for you. Because the TB bacteria are strong, you will need to take the TB infection medicine for several months (3–9 months).

It is very important to take your medicine and to keep taking it until your health care provider tells you to stop. If you miss too many days or stop taking the pills too soon, you could become sick with TB disease.

You should take your medicine, even if you don't feel sick. TB infection medicine destroys the TB bacteria in your body before they have a chance to grow, spread, and make you sick.



#### WHAT SHOULD I KNOW ABOUT MEDICINE FOR TB INFECTION?

Many people take TB infection medicine every day without any problems, but there are a few things you should watch for:

- Fever
- Poor appetite, losing weight, or feeling tired
- Nausea and vomiting
- Pain in your abdomen
- Dark urine (tea or coffee color)
- Yellow skin and eyes
- Skin rash or itching
- Numb or tingling feeling in your hands or feet
- Coughing for more than 2-3 weeks
- Sweating at night



Talk to your health care provider if you have any of these problems.

See medication information on PE-3 through PE-5.



**PATIENT EDUCATION****ISONIAZID AND RIFAPENTINE**

You have been given medicine to treat your latent TB infection. You do not have TB disease and cannot spread TB to others. This medicine will help you **PREVENT** getting TB disease.

**While on this Medicine:**

- Tell your primary care provider if you have questions or concerns with the medicine.
- Go to your weekly clinic visits. You will meet with your primary care nurse to take your medicine. This plan is called Directly Observed Therapy (DOT).
- Take all of your medicine as you were told by your primary care provider.

**TB Infection Medicine Schedule:**

Medicine	Schedule	Day	Number of pills per day	Length of Time
Isoniazid & Rifapentine	Once weekly			3 months (12 weeks)

Your primary care provider may have you take Vitamin B6 with your medicine.

NOTE: It is normal if your urine, saliva, or tears become orange-colored. Soft contact lenses may become stained.

**Watch for these Possible Problems:**

**STOP** taking your medicine right away **AND** tell your primary care nurse or provider if you have any of the problems below:

- Less appetite, or no appetite for food
- An upset stomach or stomach cramps
- Fever
- Head or body aches
- Nausea or vomiting
- Cola-colored urine or light stools
- Easy bruising or bleeding
- Rash or itching
- Yellowing skin or eyes
- Severe weakness or tiredness
- Dizziness
- Tingling or numbness in hands and feet

## PATIENT EDUCATION

## ISONIAZID

You have been given medicine to treat your latent TB infection. You do not have TB disease and cannot spread TB to others. This medicine will help you **PREVENT** getting TB disease.

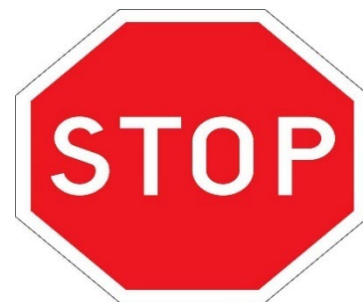
## While on this Medicine:

- Tell your primary care provider if you have questions or concerns with the medicine.
- Go to your planned clinic visits. You will meet with your primary care nurse to take your medicine. This plan is called Directly Observed Therapy (DOT).
- Take all of your medicine as you were told by your primary care provider.

## TB Infection Medicine Schedule:

Medicine	Schedule	Day	Number of pills per day	Length of Time
Isoniazid	Daily	Every Day		9 months
	Twice Daily	M T W Th F S Sun		

NOTE: It is normal if your urine, saliva, or tears become orange-colored. Soft contact lenses may become stained.



## Watch for these Possible Problems:

**STOP** taking your medicine right away **AND** tell your primary care nurse or provider if you have any of the problems below:

- Less appetite, or no appetite for food
- An upset stomach or stomach cramps
- Nausea or vomiting
- Cola-colored urine or light stools
- Easy bruising or bleeding
- Rash or itching
- Yellowing skin or eyes
- Severe weakness or tiredness
- Fever
- Head or body aches
- Dizziness

**PATIENT EDUCATION****RIFAMPIN**

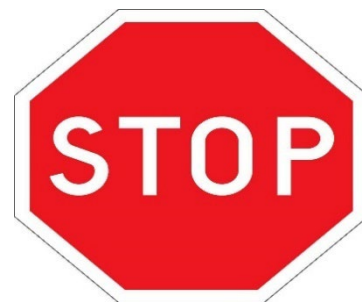
You have been given medicine to treat your latent TB infection. You do not have TB disease and cannot spread TB to others. This medicine will help you **PREVENT** getting TB disease.

**While on this Medicine:**

- Tell your primary care provider if you have questions or concerns with the medicine.
- Go to your daily clinic visits. You will meet with your primary care nurse to take your medicine. This plan is called Directly Observed Therapy (DOT).
- Take all of your medicine as you were told by your primary care provider.

**TB Infection Medicine Schedule:**

Medicine	Schedule	Day	Number of pills per day	Length of Time
Rifampin	Daily			4 months

**Watch for these Possible Problems:**

**STOP** taking your medicine right away **AND** tell your primary care nurse or provider if you have any of the problems below:

- Less appetite, or no appetite for food
- An upset stomach or stomach cramps
- Nausea or vomiting
- Cola-colored urine or light stools
- Rash or itching
- Yellowing skin or eyes
- Tingling or numbness in hands and feet

**PATIENT EDUCATION****ISONIAZID AND RIFAMPIN**

You have been given medicine to treat your latent TB infection. You do not have TB disease and cannot spread TB to others. This medicine will help you **PREVENT** getting TB disease.

**While on this Medicine:**

- Tell your primary care provider if you have questions or concerns with the medicine.
- Go to your daily clinic visits. You will meet with your primary care nurse to take your medicine. This plan is called Directly Observed Therapy (DOT).
- Take all of your medicine as you were told by your primary care provider.

**Watch for these Possible Problems:****TB Infection Medicine Schedule:**

Medicine	Schedule	Day	Number of pills per day	Length of Time
Rifampin	Daily			3 months
Isoniazid	Daily			

**STOP** taking your medicine right away **AND** tell your primary care nurse or provider if you have any of the problems below:

- Less appetite, or no appetite for food
- An upset stomach or stomach cramps
- Nausea or vomiting
- Cola-colored urine or light stools
- Easy bruising or bleeding
- Rash or itching
- Yellowing skin or eyes
- Severe weakness or tiredness
- Fever
- Head or body aches
- Dizziness
- Tingling or numbness in hands and feet

## PATIENT EDUCATION

### TUBERCULOSIS DISEASE: WHAT YOU SHOULD KNOW

#### WHAT IS TUBERCULOSIS DISEASE

Tuberculosis (TB) is a disease caused by bacteria that are spread from person to person through the air. TB bacteria are put into the air when a person with TB disease coughs, sneezes, speaks, or sings. The bacteria can stay in the air for several hours, depending on the environment. Someone who breathes in the TB bacteria can become infected (This is called latent infection. See pages PE-1 to PE-3).

You have TB disease when you have active TB bacteria in your body.

- TB disease makes you feel sick
- TB disease usually attacks the lungs
- TB disease may also occur in other parts of the body such as kidney, brain, spine, or other bones.
- People with TB disease can spread TB bacteria to other people, especially to those they are close to.



#### HOW DO I KNOW IF I HAVE TB DISEASE?

Only your health care provider can tell if you have TB disease.

If the disease is in your lungs, you may:

- Cough a lot
- Cough up mucus
- Cough up blood
- Have chest pain when you cough



You may also:

- Feel weak
- Lose your appetite
- Lose weight
- Have a fever
- Sweat a lot at night

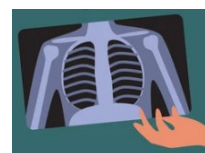
These symptoms may last for many weeks. They usually get worse and you could die without treatment.

TB disease outside the lungs may cause other symptoms.

#### HOW IS TB DISEASE DIAGNOSED?

TB disease is diagnosed by a health care provider using:

- The symptoms you are having
- Your physical examination
- Your chest x-ray
- Performing cultures on collected sputum. Results may take weeks before the result is final.



#### HOW IS TB DISEASE TREATED?

- TB disease can be cured with medicine
- You will be separated from other people until you are no longer able to spread TB bacteria. This separation is usually not very long if you take your medicine as ordered by your health care provider
- Missing doses will increase the duration of your treatment and it can cause your treatment to fail
- Your health care provider may order laboratory tests or chest x-rays during your treatment

## PATIENT EDUCATION

### TUBERCULOSIS DISEASE: WHAT YOU SHOULD KNOW, Continued

#### WHAT SHOULD I LOOK FOR WHEN TAKING TB MEDICATIONS?

Tell your health care provider if you have:

- A fever
- A rash
- Aching joints
- Aches or tingling in fingers or toes
- Stomach upset, nausea, or stomach cramps
- Vomiting
- Changes in eyesight such as blurred vision
- Changes in hearing such as ringing in your ears
- Dizziness
- Bruising
- Easy bleeding with cuts
- Less appetite or no appetite for food
- Tingling and numbness around the mouth
- Yellow skin or eyes



Tell your health care team right away if you think you are having any reaction to your treatment.

Your health care provider will find a medicine plan that works for you.

Most people can take their TB medicines without any problems.

#### WHAT ELSE SHOULD I KNOW?

- Even if you feel better after a few weeks of treatment it does not mean the TB bacteria in your body are dead.
- Treatment for TB disease takes a long time (6 months or longer) because TB bacteria die very slowly.
- It is important to take all of the medicines you are given exactly as they are prescribed and not to miss **ANY** doses.

#### WHAT IS A TB CONTACT INVESTIGATION?

- If you have active TB disease, it is very important to find out if the disease has spread to other people.
- When health care workers look to see if the disease has spread, it is called a contact investigation.
- If TB has spread to other people, they will need to be tested and may need medicine so they don't get sick.
- Information you give to a health care worker during a contact investigation is confidential.

## PATIENT EDUCATION

### TUBERCULOSIS TESTING: TB SKIN TEST

#### WHAT YOU SHOULD KNOW ABOUT THE TB SKIN TEST

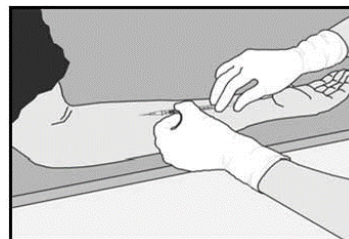
Getting tested and treated for TB can protect you and those around you from getting sick. There are two types of tests for TB infection: The TB blood test and TB skin test. This page gives you information on the TB skin test.

#### TB SKIN TEST: WHAT YOU SHOULD KNOW

The TB skin test may be used to find out if you are infected with TB bacteria. A health care provider will inject a small amount of testing fluid into the skin in the lower part of your inner arm.

After Receiving the TB Skin Test:

- Do not cover the spot with a bandage or tape
- Do not use lotion on the test area
- Be careful not to rub or scratch it
- If the spot itches, put a cold cloth on it
- You can wash your arm and dry it gently



You must return after 2-3 days to have a trained health care provider look for any reaction on your arm.



**Return to have your skin test read on:**

**Date:** \_\_\_\_\_

**Time:** \_\_\_\_\_

**Location:** \_\_\_\_\_

You may have swelling or a bump where the testing fluid was injected. The health care provider will measure the size of the swelling or bump to see if the test is positive or negative. If there is a bump, it will go away in a few weeks.

If your TB skin test is <b>POSITIVE</b> :	If your TB skin test is <b>NEGATIVE</b> :
<ul style="list-style-type: none"> <li>• You have TB bacteria in your body.</li> <li>• The test does not tell whether you have inactive (latent) TB or active TB disease.</li> <li>• You will need other tests, such as a physical exam, chest x-ray, and lab work to see if you have active TB disease.</li> <li>• Once you test positive for TB, you will always have a positive test, even if you complete TB treatment.</li> <li>• Tell your health care provider if you have had TB treatment in the past.</li> </ul>	<ul style="list-style-type: none"> <li>• Your body did not react to the test. You likely do not have inactive TB or active TB disease:</li> <li>• You may need more tests if:               <ul style="list-style-type: none"> <li>○ You have symptoms of active TB disease, like coughing, chest pain, fever, weight loss, or tiredness.</li> <li>○ You have HIV infection.</li> <li>○ Your exposure to TB was recent. You may need a second skin test 8 to 10 weeks after the last time you spent time with someone with active TB disease. This is because it can take several weeks after infection for your immune system to react to the TB skin test. If your reaction to the second test is negative, you likely do not have inactive TB or active TB disease.</li> </ul> </li> </ul>

**PATIENT EDUCATION****TUBERCULOSIS TESTING: BCG VACCINE AND TB BLOOD TEST****WHAT IF I HAD A BACILLE CALMETTE-GUÉRIN (BCG) TB VACCINE?**

- BCG is a vaccine for TB. It is not used much in the United States. If you were born in another country, you may have had a BCG vaccine for TB.
- The BCG vaccine is often given to infants and small children in countries where TB is more common. Protection from TB goes away as people get older.

**Tell your health care provider if you know you were vaccinated with BCG vaccine.**

- BCG vaccination does not completely prevent people from getting TB and you can still get latent TB infection or active TB disease.
- You can still have a TB skin test or TB blood test if you had a BCG vaccine, but it may cause a positive TB skin test even if you are not infected with TB bacteria.
- The TB blood test is not affected by the BCG vaccine and is the preferred test for those who have been vaccinated.

**TB BLOOD TEST: WHAT YOU SHOULD KNOW**

- TB blood tests, called Interferon-Gamma Release Assays (IGRAs) are blood tests that can determine if a person has been infected with TB bacteria. The IGRA measures how your immune system reacts to TB bacteria.
- To do the test, a small amount of blood is collected in special tubes and sent to a laboratory for testing. Results are sent to your health care provider.
- A positive test means you have been infected with TB bacteria. Other tests will be needed to see if you have latent TB infection or active TB disease.
- A negative test means your blood did not react to the test and that TB infection or TB disease is not likely.



## EDUCACIÓN PARA PACIENTES

### INFECCIÓN DE TUBERCULOSIS LATENTE: LO QUE DEBE SABER

#### ¿QUÉ ES LA INFECCIÓN DE TUBERCULOSIS LATENTE?

La infección de tuberculosis (TB) latente es una infección causada por bacterias o gérmenes de la TB que se transmiten de una persona a otra a través del aire. Si ha pasado tiempo cerca de alguien con la enfermedad de TB activa, usted podría haber inhalado la bacteria de la TB a sus pulmones.

Si ha pasado tiempo con alguien que tiene la enfermedad de TB activa, debe hablar con su equipo de atención médica sobre la posibilidad de hacerse la prueba de la TB.

Una persona con infección de TB latente no puede contagiar la bacteria a otras personas. Si usted ha pasado tiempo con alguien con infección de TB latente, no necesita hacerse la prueba de la TB.



#### ¿CUÁLES SON LOS SÍNTOMAS DE LA INFECCIÓN DE TUBERCULOSIS LATENTE?

Si usted tiene una infección de tuberculosis latente, las bacterias de la tuberculosis están vivas en su cuerpo, sin embargo, en este momento no le hacen daño.

La infección de tuberculosis latente no presenta síntomas. Las bacterias de la tuberculosis están adormecidas en su cuerpo, pero podrían empezar a crecer y propagarse. Cuando las bacterias crecen y se propagan, se denomina la enfermedad de TB activa. Las personas con TB activa pueden enfermarse gravemente y contagiar la enfermedad a otras personas.

**Esto puede sucederle a cualquier persona con infección de TB latente en cualquier momento, sin embargo, hay medicamentos que puede tomar para evitar enfermarse en el futuro.**

#### ¿CÓMO SÉ SI TENGO LA INFECCIÓN DE TB?

Un análisis de sangre para la TB o una prueba cutánea para la TB mostrarán si padece una infección por TB. Si le dicen que la prueba de la TB es positiva, recibirá:

3. Una radiografía de tórax (RxT) para comprobar si tiene TB en los pulmones.
4. Un examen físico para asegurarse de que no tiene la enfermedad de TB en otras partes del cuerpo.

Si el médico le dice que la radiografía de tórax es normal y usted no tiene síntomas de TB activa en el cuerpo, le dirá que tiene la infección de TB.

Consulte las páginas PE-9 y PE-10 para obtener información sobre las pruebas de TB.

#### ¿TODAS LAS PERSONAS CON INFECCIÓN DE TUBERCULOSIS LATENTE CORREN EL RIESGO DE CONTRAER LA ENFERMEDAD DE TB ACTIVA?

Todas las personas con infección de TB latente corren el riesgo de que las bacterias de la TB se propaguen y se conviertan en la enfermedad de TB. El riesgo de contraer la tuberculosis es aún mayor durante los dos primeros años después de contraer la infección por TB. Algunas personas tienen afecciones que hacen que tengan un riesgo aún mayor de que esto ocurra. Hable con su proveedor de atención médica si tiene:

- Infección del VIH
- Otros problemas de salud, como diabetes
- Abuso de alcohol o consumo de drogas ilegales
- Ha tomado antes medicamentos para la TB, pero no ha completado el tratamiento

**EDUCACIÓN PARA PACIENTES****INFECCIÓN DE TUBERCULOSIS LATENTE: LO QUE DEBE SABER (continuación)****SI TENGO UNA INFECCIÓN DE TUBERCULOSIS LATENTE, ¿CÓMO PUEDO PREVENIR LA ENFERMEDAD DE TUBERCULOSIS ACTIVA?**

Si tiene una infección de tuberculosis latente, existen medicamentos que puede tomar para evitar contraer la enfermedad de la TB. Los medicamentos antituberculosos destruyen las bacterias adormecidas de la TB antes de que puedan provocarle la enfermedad.



Su proveedor de atención médica le recetará el medicamento para la infección de TB más adecuado para usted. Como la bacteria de la TB es muy fuerte, usted deberá tomar el medicamento para la infección por TB durante varios meses (de 3 a 9 meses).

Es muy importante tomar el medicamento y seguir tomándolo hasta que el médico le diga que lo suspenda. Si no toma las pastillas durante varios días o deja de tomarlas demasiado pronto, usted puede contraer la enfermedad de la TB.

Debe tomar el medicamento aunque no se sienta mal. El medicamento para la infección de TB destruye las bacterias de la TB de su cuerpo antes de que tengan la oportunidad de crecer, propagarse y enfermarlo.

**¿QUÉ DEBO SABER SOBRE LOS MEDICAMENTOS PARA LA INFECCIÓN POR TB?**

Muchas personas toman medicamentos contra la TB todos los días sin ningún problema, pero hay algunas cosas que debe tener en cuenta:

- Fiebre
- Falta de apetito, pérdida de peso o sensación de cansancio
- Náuseas y vómitos
- Dolor abdominal
- Orina oscura (color té o café)
- Piel y ojos amarillos
- Erupción cutánea o picazón
- Sensación de entumecimiento u hormigueo en manos o pies
- Tos durante más de 2-3 semanas
- Transpiración nocturna



Hable con su médico si tiene alguno de estos problemas.

Consulte información sobre el medicamento de PE-3 a PE-5.

## EDUCACIÓN PARA PACIENTES

## ISONIAZIDA Y RIFAPENTINA

Le han dado medicamentos para tratar su infección de tuberculosis latente. No tiene la enfermedad de tuberculosis y no puede contagiarla a otras personas. Este medicamento le ayudará a **PREVENIR** la TB.

## Mientras tome este medicamento:

- Si tiene preguntas o dudas sobre este medicamento, comuníquese con su médico de cabecera.
- Acuda a sus consultas clínicas semanales. Se reunirá con su enfermera de cabecera para tomar su medicamento. Este plan se llama Terapia por Observación Directa (DOT, por sus siglas en inglés).
- Tome todos sus medicamentos como le indicó su médico de cabecera.

## Calendario de medicamentos contra la infección de TB:

Medicamento	Horario	Día	Cantidad de pastillas por día	Duración
Isoniazida y rifapentina	Una vez por semana			3 meses (12 semanas)

Su médico de cabecera puede indicarle que tome Vitamina B6 junto con sus medicamentos.

**OBSERVACIÓN:** Es normal que su orina, saliva o lágrimas adquieran un color anaranjado. Las lentes de contacto blandas pueden mancharse.



## Esté atento a estos posibles problemas:

**DEJE** de tomar sus medicamentos de inmediato **Y** comuníquese con su enfermera o médico de cabecera si tiene alguno de los problemas que se indican a continuación:

- Menos o nada de apetito
- Malestar estomacal o cólicos estomacales
- Fiebre
- Dolores de cabeza o corporales
- Náuseas o vómitos
- Orina de color refresco de Cola o heces ligeras
- Fácil aparición de oretones o hemorragias
- Erupción cutánea o picazón
- Ojos o piel amarillentos
- Debilidad o cansancio extremo
- Mareos
- Hormigueo o entumecimiento de manos y pies

## EDUCACIÓN PARA PACIENTES

## ISONIAZIDA

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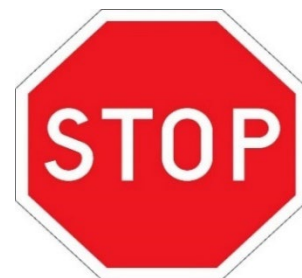
## Mientras tome este medicamento:

- Si tiene preguntas o dudas sobre este medicamento, comuníquese con su médico de cabecera.
- Asista a las consultas clínicas programadas. Se reunirá con su enfermera de cabecera para tomar su medicamento. Este plan se llama Terapia por Observación Directa (DOT, por sus siglas en inglés).
- Tome todos sus medicamentos como le indicó su médico de cabecera.

## Calendario de medicamentos contra la infección de TB:

Medicamento	Horario	Día	Cantidad de pastillas por día	Duración
Isoniazida	A diario	Todos los días		9 meses
	Dos veces al día	L Ma Mi J V S D		

**OBSERVACIÓN:** es normal que su orina, saliva o lágrimas adquieran un color anaranjado. Las lentes de contacto blandas pueden mancharse.



## Esté atento a estos posibles problemas:

**DEJE** de tomar sus medicamentos de inmediato **Y** comuníquese con su enfermera o médico de cabecera si tiene alguno de los problemas que se indican a continuación:

- Menos o nada de apetito
- Malestar estomacal o cólicos estomacales
- Náuseas o vómitos
- Orina de color refresco de Cola o heces ligeras
- Fácil aparición de moretones o hemorragias
- Erupción cutánea o picazón
- Ojos o piel amarillentos
- Debilidad o cansancio extremo
- Fiebre
- Dolores de cabeza o corporales
- Mareos

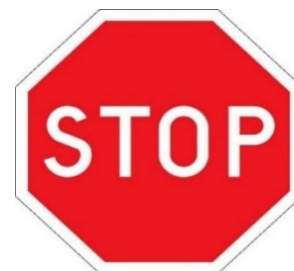
## EDUCACIÓN PARA PACIENTES

## RIFAMPICINA

Le han dado medicamentos para tratar su infección de tuberculosis latente. No tiene la enfermedad de tuberculosis y no puede contagiarla a otras personas. Este medicamento le ayudará a **PREVENIR** la TB.

## Mientras tome este medicamento:

- Si tiene preguntas o dudas sobre este medicamento, comuníquese con su médico de cabecera.
- Asista a las consultas clínicas diarias. Se reunirá con su enfermera de cabecera para tomar su medicamento. Este plan se llama Terapia por Observación Directa (DOT, por sus siglas en inglés).
- Tome todos sus medicamentos como le indicó su médico de cabecera.



**Esté atento a estos posibles problemas:**

## Calendario de medicamentos contra la infección de TB:

Medicamento	Horario	Día	Cantidad de pastillas por día	Duración
Rifampicina	A diario			4 meses

**DEJE** de tomar sus medicamentos de inmediato **Y** comuníquese con su enfermera o médico de cabecera si tiene alguno de los problemas que se indican a continuación:

- Menos o nada de apetito
- Malestar estomacal o cólicos estomacales
- Náuseas o vómitos
- Orina de color refresco de Cola o heces ligeras
- Erupción cutánea o picazón
- Ojos o piel amarillentos
- Hormigueo o entumecimiento de manos y pies

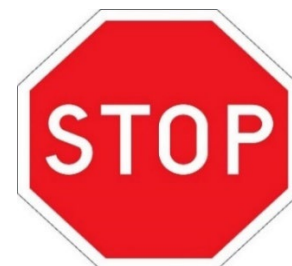
## EDUCACIÓN PARA PACIENTES

## ISONIAZIDA Y RIFAMPICINA

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**Esté atento a estos posibles problemas:**

## Calendario de medicamentos contra la infección de TB:

Medicamento	Horario	Día	Cantidad de pastillas por día	Duración
Rifampicina	A diario			3 meses
Isoniazida	A diario			

**DEJE** de tomar sus medicamentos de inmediato **Y** comuníquese con su enfermera o médico de cabecera si tiene alguno de los problemas que se indican a continuación:

- Menos o nada de apetito
- Malestar estomacal o cólicos estomacales
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- Fácil aparición de moretones o hemorragias
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- Fiebre
- Dolores de cabeza o corporales
- Mareos
- Hormigueo o entumecimiento de manos y pies

## EDUCACIÓN PARA PACIENTES

### ENFERMEDAD DE TUBERCULOSIS: LO QUE DEBE SABER

#### ¿QUÉ ES LA ENFERMEDAD DE TUBERCULOSIS?

La tuberculosis (TB) es una enfermedad causada por bacterias que se propagan de persona a persona a través del aire. Las bacterias de la TB se liberan en el aire cuando una persona con TB tose, estornuda, habla o canta. Las bacterias pueden permanecer en el aire durante varias horas, dependiendo del ambiente. Una persona que respira la bacteria de la TB puede infectarse (esto se denomina infección latente. Consulte las páginas PE-1 a PE-3).

Se padece la enfermedad de la TB cuando hay bacterias de la TB activas en el organismo.

- La TB le hace sentirse mal
- La TB suele afectar a los pulmones
- La TB también puede afectar a otras partes del cuerpo, como los riñones, el cerebro, la columna vertebral u otros huesos.
- Las personas con TB pueden contagiar la bacteria de la TB a otras personas, especialmente a las que están a su alrededor.



#### ¿CÓMO SÉ SI TENGO LA ENFERMEDAD DE LA TB?

Sólo su médico puede decirle si tiene TB.

Si la enfermedad está en sus pulmones, usted puede:

- Toser mucho
- Toser con flemas
- Toser con sangre
- Tener dolor en el pecho al toser



Usted también puede:

- Sentirse débil
- Perder el apetito
- Adelgazar
- Tener fiebre
- Transpirar mucho por la noche

Estos síntomas pueden durar muchas semanas. Suelen empeorar y usted podría morir si no recibe tratamiento. La TB fuera de los pulmones puede causar otros síntomas.

#### ¿CÓMO SE DIAGNOSTICA LA ENFERMEDAD DE LA TB?

El profesional médico diagnostica la TB mediante:

- Los síntomas que presenta
- Su examen físico
- Su radiografía de tórax
- Cultivos de una muestra de esputo. Los resultados pueden tardar semanas en ser definitivos.



#### ¿CÓMO SE TRATA LA ENFERMEDAD DE LA TB?

- La enfermedad de la TB se cura con medicamentos
- Estará separado de otras personas hasta que ya no pueda propagar la bacteria de la TB. Esta separación no suele ser muy larga si toma su medicamento según las indicaciones de su médico
- La omisión de la dosis aumentará la duración del tratamiento y puede hacer que éste fracase
- El médico puede solicitar pruebas de laboratorio o radiografías de tórax durante el tratamiento

## EDUCACIÓN PARA PACIENTES

### ENFERMEDAD DE TUBERCULOSIS: LO QUE DEBE SABER (continuación)

#### ¿QUÉ DEBO TENER EN CUENTA AL TOMAR MEDICAMENTOS CONTRA LA TB?

Informe a su médico si tiene:

- Fiebre
- Erupción cutánea
- Dolor en las articulaciones
- Hormigueo en los dedos de las manos o de los pies
- Malestar estomacal, náuseas o cólicos estomacales
- Vómitos
- Cambios en la vista como visión borrosa
- Cambios en la audición, como zumbidos en los oídos
- Mareos
- Moretones
- Sangrado fácil con cortes
- Menos o nada de apetito
- Hormigueo y entumecimiento alrededor de la boca
- Ojos o piel amarillentos



Informe inmediatamente a su equipo médico si cree que está teniendo alguna reacción al tratamiento.

Su médico encontrará un plan de medicamentos que funcione para usted.

La mayoría de las personas pueden tomar sus medicamentos para la TB sin problemas.

#### ¿QUÉ MÁS DEBERÍA SABER?

- Aunque se sienta mejor después de unas semanas de tratamiento, eso no significa que las bacterias de la TB en su organismo estén muertas.
- El tratamiento de la enfermedad de tuberculosis es largo (6 meses o más) porque las bacterias de la tuberculosis mueren muy lentamente.
- Es importante que tome todos los medicamentos exactamente como se le receten y que no omita **NINGUNA** dosis.

#### ¿QUÉ ES UNA INVESTIGACIÓN DE CONTACTOS DE TB?

- Si tiene tuberculosis activa, es muy importante averiguar si la enfermedad se ha transmitido a otras personas.
- Cuando el personal médico comprueba si la enfermedad se ha propagado, se denomina investigación de contactos.
- Si la TB se ha propagado a otras personas, habrá que hacerles pruebas y es posible que necesiten medicamentos para no enfermarse.
- La información que usted proporcione a un trabajador de la salud durante una investigación de contacto es confidencial.



## EDUCACIÓN PARA PACIENTES

### PRUEBAS DE TUBERCULOSIS: PRUEBA CUTÁNEA DE LA TUBERCULOSIS

#### LO QUE DEBE SABER SOBRE LA PRUEBA CUTÁNEA DE LA TB

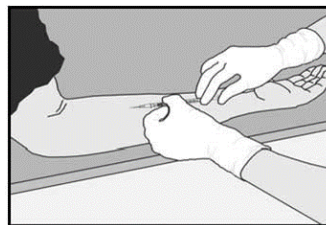
Hacerse la prueba y someterse al tratamiento de la TB puede protegerlo a usted y a los que le rodean de contraer la enfermedad. Existen dos tipos de pruebas para detectar la infección por TB: el análisis de sangre de la TB y la prueba cutánea de la TB. En esta página encontrará información sobre la prueba cutánea de la TB.

#### PRUEBA CUTÁNEA DE LA TB: LO QUE DEBE SABER

La prueba cutánea de la TB puede utilizarse para averiguar si está infectado por la bacteria de la TB. Un médico le inyectará una pequeña cantidad de líquido de prueba en la piel, en la parte inferior de la cara interna del brazo.

Después de la prueba cutánea de la TB:

- No cubra la zona de la prueba con una venda o cinta adhesiva
- No utilice loción en la zona de la prueba
- Tenga cuidado de no frotarse ni rascarse
- Si le pica la zona, póngase un paño frío
- Puede lavarse el brazo y secarlo suavemente



Debe volver al cabo de 2 o 3 días para que un profesional de la salud capacitado observe si tiene alguna reacción en el brazo.



**Vuelva para que le lean la prueba cutánea:**

Fecha: \_\_\_\_\_

Hora: \_\_\_\_\_

Lugar: \_\_\_\_\_

Es posible que tenga hinchazón o una protuberancia en el lugar donde se inyectó el líquido de prueba. El profesional de la salud medirá el tamaño de la hinchazón o protuberancia para ver si la prueba es positiva o negativa. Si hay una protuberancia, desaparecerá en unas semanas.

Si la prueba cutánea de la TB es POSITIVA:	Si la prueba cutánea de la TB es NEGATIVA:
<ul style="list-style-type: none"> <li>• Tiene la bacteria de la TB en su cuerpo.</li> <li>• La prueba no indica si tiene TB inactiva (latente) o TB activa.</li> <li>• Usted necesitará otras pruebas, como un examen físico, una radiografía de tórax y análisis de laboratorio, para saber si tiene la enfermedad de TB activa.</li> <li>• Una vez que dé positivo en la prueba de la TB, siempre tendrá un resultado positivo, aunque complete el tratamiento contra la TB.</li> <li>• Informe a su médico si ha recibido un tratamiento contra la TB en el pasado.</li> </ul>	<ul style="list-style-type: none"> <li>• Su cuerpo no reaccionó a la prueba. Es probable que no tenga TB inactiva ni TB activa:</li> <li>• Es posible que necesite más pruebas si: <ul style="list-style-type: none"> <li>○ Tiene síntomas de TB activa, como tos, dolor torácico, fiebre, pérdida de peso o cansancio.</li> <li>○ Está infectado con el VIH.</li> <li>○ Su exposición a la TB ha sido reciente. Es posible que necesite una segunda prueba cutánea entre 8 y 10 semanas después de la última vez que estuvo con una persona con la enfermedad de TB activa. Esto se debe a que su sistema inmunitario puede tardar varias semanas después de la infección en reaccionar a la prueba cutánea de la TB. Si su reacción a la segunda prueba es negativa, es probable que no tenga TB inactiva ni TB activa.</li> </ul> </li> </ul>

**EDUCACIÓN PARA PACIENTES****PRUEBAS DE TUBERCULOSIS: VACUNA BCG Y ANÁLISIS DE SANGRE PARA LA TB****¿Y SI ME HUBIERA VACUNADO CONTRA LA TB CON EL BACILO CALMETTE-GUÉRIN (BCG, POR SUS SIGLAS EN INGLÉS)?**

- El BCG es una vacuna contra la TB. No se utiliza mucho en Estados Unidos. Si nació en otro país, es posible que le hayan aplicado la vacuna BCG contra la TB.

- La vacuna BCG suele administrarse a bebés y niños pequeños en países donde la TB es más común. La protección contra la TB desaparece con la edad.

**Informe a su proveedor de atención médica si sabe que fue vacunado con la vacuna BCG.**

- La vacuna BCG no evita por completo que las personas contraigan TB y usted aún puede contraer la infección de TB latente o la enfermedad de TB activa.
- Puede hacerse una prueba cutánea de la TB o un análisis de sangre de la TB si se vacunó con la BCG, pero puede dar positivo en la prueba cutánea de la TB aunque no esté infectado con la bacteria de la TB.
- El análisis de sangre de la TB no se ve afectado por la vacuna BCG y es la prueba de preferencia para los vacunados.

**ANÁLISIS DE SANGRE DE LA TB: LO QUE DEBE SABER**

- Los análisis de sangre para la TB, denominados Ensayos de Liberación de Interferón-Gamma (IGRA, por sus siglas en inglés) son análisis de sangre que pueden determinar si una persona ha sido infectada por la bacteria de la TB. El IGRA mide cómo reacciona su sistema inmunitario ante la bacteria de la TB.
- Para realizar la prueba, se extrae una pequeña cantidad de sangre en tubos especiales y se envía al laboratorio para su análisis. Los resultados se envían a su médico.
- Un resultado positivo significa que está infectado por la bacteria de la TB. Se necesitarán otras pruebas para determinar si tiene la infección de TB latente o la enfermedad de TB activa.
- Una prueba negativa significa que su sangre no reaccionó a la prueba y que la infección por TB o la enfermedad por TB están descartadas.