

## Summary of Important Los Angeles County Tuberculosis Control Program Treatment Guidelines for Private and Community Medical Providers

---

### 1. Reporting - Confidential Morbidity Report (CMR) FAX Reporting Form

- All health care providers are mandated to report within one (1) day of diagnosis all patients with suspected or confirmed tuberculosis (TB) (California Health and Safety Code, Division 4, Chapter 5, Sections 121361 and 121362).
- Prior to discharge, all patients under evaluation and confirmed with TB in hospitals have an individualized, written discharge plan approved by the Tuberculosis Control Program (California Health and Safety Code, Division 4, Chapter 5, Section 121361).
- All health care providers are mandated to provide information related to the treatment of patients under evaluation or confirmed with TB disease to ensure that individuals under evaluation and treatment for TB disease are receiving timely diagnosis and effective treatment (California Health and Safety Code, 121362).
- The County of Los Angeles, Department of Public Health, is mandated to maintain a record of clinical follow-up of all TB patients (California Health and Safety Code, Division 4, Chapter 5, Section 121362). The public health nurse assigned as a case manager for your patient will be requesting information about your patient's clinical care that is needed for the required public health surveillance reporting. Please see attachment for an example of the information needed.

### 2. HIV testing for persons with suspected and confirmed TB disease is the national and local standard of care. [https://www.cdc.gov/tb-programs/php/ntip/objectives-and-performance-targets.html?CDC\\_AAref\\_Val=https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm](https://www.cdc.gov/tb-programs/php/ntip/objectives-and-performance-targets.html?CDC_AAref_Val=https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm)

### 3. Initial TB Treatment Guidelines

- **Isoniazid (INH) Susceptibility Not Known and if Xpert MTB/RIF assay does not show RIF resistance detected:**
  - Initiate one of the following empiric first-line regimens no later than 7 days after the date of laboratory confirmation of TB diagnosis:
    - INH with vitamin B6 supplementation (INH/B6) + Rifampin + Pyrazinamide + Ethambutol (HRZE) given for at least two (2) months (four drugs daily);
    - Alternatively, may consider INH/B6 + high-dose daily Rifapentine + Moxifloxacin + Pyrazinamide (HPMZ) given for 8 weeks (four drugs daily)\*.
    - Rifabutin administered daily may be substituted for Rifampin in the HRZE regimen, if this is deemed necessary due to clinical considerations such as potential drug-drug interactions. However, Rifabutin is NOT an acceptable substitute for Rifapentine in the HPMZ regimen.
  - For detailed guidance on dosing of first-line anti-TB treatment regimens, please see: <http://ph.lacounty.gov/tb/docs/LACTBDrugRegimens.pdf>



- Patients on either of the above regimens should be seen at least monthly for a history and physical examination, and bloodwork while on anti-TB treatment to manage side effects and monitor for toxicity.
- For detailed guidance on monitoring patients who are receiving anti-TB treatment, please see: [http://ph.lacounty.gov/tb/docs/nonDPH-TB\\_DrugMonitoringPolicy.pdf](http://ph.lacounty.gov/tb/docs/nonDPH-TB_DrugMonitoringPolicy.pdf) and <http://ph.lacounty.gov/tb/docs/TBMonitoringGuidelines-Treatment.pdf>.
- **If Xpert MTB/RIF assay shows Rifampin-RESISTANCE DETECTED or INDETERMINATE, or other molecular or phenotypic drug susceptibilities indicate resistance to INH, Rifampin, Ethambutol, Pyrazinamide, or fluoroquinolones, then immediately refer patient to the Department of Public Health (DPH) for clinical care, including extended molecular and/or phenotypic drug susceptibility testing, and procurement and administration of second-line anti-TB drugs via Directly Observed Therapy (DOT).**

\*Do not advise starting this regimen unless adequate Rifampine drug supply is secured by the dispensing pharmacy for the entire four-month (17-week) HPMZ regimen for each eligible patient; additional testing is needed to ensure susceptibility to all drugs including pyrazinamide and fluoroquinolones. Consultation with the designated DPH clinician is advised to determine eligibility for this regimen.

#### 4. With culture confirmation and laboratory susceptibility data:

- **If the isolate has been confirmed via laboratory testing to be fully susceptible to all four first-line drugs and the patient has completed standard INH/B6 + Rifampin + Ethambutol + Pyrazinamide for at least two months (8 weeks) within 10 weeks of anti-TB treatment initiation**
  - Continue INH/B6 + Rifampin for at least four (4) months.
  - Pyrazinamide and Ethambutol may be discontinued.
  - Complete a total of six to nine (6-9) months of adequate rifamycin-based anti-TB therapy.
  - Patients with baseline cavitary pulmonary TB disease AND persistent positive sputum cultures at or after 8 weeks should receive a minimum of nine (9) months of adequate rifamycin-based anti-TB therapy.
  - Please note that recurrent national reagent shortages have resulted in delayed or absent phenotypic drug susceptibility test results for pyrazinamide. Treatment extension to a total of nine (9) months should be considered for patients with unknown phenotypic or molecular susceptibility to pyrazinamide, especially if risk factors or clinical features consistent with *MTB* var. *bovis* are identified. Clinical consultation with TBCP is recommended.
  - Minimum required duration of therapy may also need to be extended due to severity and sites of disease, comorbid conditions, intolerance of or resistance to first-line drugs, treatment interruptions or non-adherence, and other factors.
  - Consult the designated DPH clinician for individualized recommendations regarding total duration of therapy.



- **If the isolate has resistance to any of the first-line drugs, immediately refer patient to the Department of Public Health (DPH) for clinical care, as per above.**

## 5. Directly Observed Therapy (DOT)

- The best practice standard of care for TB treatment in the United States is to receive anti-TB treatment by DOT, as DOT ensures that patients complete an adequate course of TB treatment.
- DOT is defined as daily delivery of medication doses by a health care worker who observes and documents that the patient ingests or is injected with the medication, monitors them for adverse events, and serves as an additional point of contact for access to social support.
- In LA County, DOT is provided via multiple modes of delivery by trained personnel at DPH.
- Delivery alone to the patient without observation and documentation is not DOT.
- In LA County, the following patients with TB under evaluation (American Thoracic Society (ATS) Class TB-5) and confirmed TB disease (ATS Class TB-3) are required to receive DOT and receive clinical care from LA County DPH:
  - People with HIV infection
  - Current substance use disorder
  - Person experiencing homelessness
  - History of previous TB disease
  - Lab results showing resistance to one or more anti-TB drugs
  - Incarceration with current episode of TB
  - Failure to respond to anti-TB therapy
  - Non-daily anti-TB regimen
  - Nonadherence to anti-TB regimen during current episode of TB disease
  - On Health Officer Order
  - Patient without adequate health insurance coverage for all required components of outpatient TB care
- Other potential indications that may warrant DOT and clinical care from LA County DPH include:
  - Congregate living without nursing support
  - Inability to care for oneself without strong caregiver support
  - Age under 5-years-old
  - Transient residency in LA County
- For patients under the clinical care of private or community providers and initiated on anti-TB treatment, a district Public Health Nurse is assigned as a case manager to provide pill counts of anti-TB medication; assess the patient's ability to adhere to the TB treatment plan; educate about TB pathogenesis, transmission, treatment and prevention; identify and provide treatment adherence supports for which the patient may be eligible; and conduct TB Contact Investigation.



- If your patient is experiencing drug toxicity or intolerance, you may request a referral for DPH TB care that will include DOT at one of our Health Centers through your assigned district public health nurse.

**6. Isolation:** In most cases, a person with pulmonary TB disease (ATS class 3 or class 5) can be released from isolation once they meet the following standard criteria while receiving treatment via self-administered therapy by a private or community medical provider:

- **Effective treatment:** The patient has tolerated a stable and likely effective multi-drug TB treatment regimen and is showing clinical evidence of improvement or stability, e.g. resolution of fever, decreased cough and sputum production, weight gain:
  - For AFB smear-negative disease, at least 5 continuous days of a stable and likely effective multidrug treatment regimen with good adherence.
  - For AFB smear-positive disease, at least 14 continuous days of a stable and likely effective multidrug treatment regimen with good adherence, AND either sputum AFB smear-conversion (3 consecutive negative AFB smears without a subsequent positive) or AFB culture-conversion (2 consecutive negative AFB cultures without a subsequent positive).
- For suspected or confirmed drug-resistant TB, please refer to DPH for continued TB clinical care, which will include individualized determination for de-isolation criteria.

## 7. Sputum and Chest Radiograph

- For all patients under evaluation for TB disease for pulmonary or extrapulmonary disease, initial chest radiography and three sputum smears and cultures for AFB collected at least 8 hours apart are recommended. Additionally, at least two of three sputum specimens collected should include a nucleic acid amplification test for TB.
- Monthly sputum specimens for AFB smear and culture are obtained on ALL TB cases after initiation of therapy for at least two (2) months AND until at least two final consecutive negative cultures are obtained after a positive culture for TB.
- Additional specimens should be collected on a more frequent basis, e.g., weekly, in any patient that continues to remain smear positive after one month of treatment and/or is still culture positive after 2 months of treatment or appears to be responding slowly to treatment until an appropriate response is documented. Consideration should be given to referral of such patients to DPH for continued TB clinical care, including DOT.
- High-quality sputum can be obtained by collecting an expectorated sample first thing in the morning, immediately after waking up. The mucociliary clearance that occurs overnight often yields more productive sputum.
  - Induced sputum - inhaling an aerosolized sterile hypertonic saline (3–5%) solution can stimulate sputum production.
  - Alternative methods: For children or others unable to produce sputum, alternative methods such as gastric aspiration, stool collection, or bronchoscopy may be used.



Tuberculosis Control Program  
123 W. Manchester Blvd. Rm. 228  
Inglewood, CA 90301  
Phone: (213) 745-0800; Fax: (213) 749-0926

- Requests for induced sputum through a DPH clinic when spontaneous early morning expectorated specimens cannot be collected should be requested through the patient's DPHN or DPH clinician consultant
- Repeat chest radiograph of patients with pulmonary TB disease is recommended at 2 to 3 months after start of therapy, and then approximately every 3 months until completion of therapy.

#### **8. Contact Investigation Service Conducted by Public Health Nurse**

- Contact investigation is an epidemiological investigation that must be done for every new reported laboratory-confirmed index case of pulmonary TB disease and is an essential component of reducing transmission of TB in the community
- Contact investigation allows for early detection and treatment of new infection in persons who are documented to have had close contact with an infectious person with TB disease.
- Contact investigation identifies, examines, and evaluates all persons who are at risk of infection with TB due to recent exposure to a person with confirmed pulmonary TB disease or on treatment for possible TB. Children < 5 years old with a diagnosis of TB disease require an investigation to determine the source case.
- If you are the treating provider for individuals who are close contacts to your patient, a public health nurse will request information about the evaluation and treatment of these exposed individuals.

