

*County of Los Angeles Department of Health Services
Tuberculosis Control Program Standards*

**Targeted Skin Testing and Treatment of
Latent Tuberculosis Infection in Adults and Children**

The following official LAC standards are based on CDC/ATS, California Tuberculosis Controllers Association, and California Department of Health Services, Tuberculosis Control Branch official guidelines

Recently published guidelines from the American Thoracic Society and Centers for Disease Control and Prevention have recommended a change in nomenclature. The terms “chemoprophylaxis” and “preventive therapy” will no longer be used. Instead, the phrase “treatment of latent tuberculosis infection (LTBI)” is recommended because it more accurately describes the intended intervention. This change in nomenclature will hopefully promote greater understanding of the concept for both patients and providers, resulting in more widespread use of this important tuberculosis (TB) control strategy. (see **Appendix 4 for Definitions and Abbreviations**)

Targeted TB Skin Testing

Targeted tuberculin skin testing for LTBI aims to identify individuals at high risk for TB who would benefit from treatment of LTBI. Persons for whom treatment of LTBI is indicated in this document are the same categories of persons who should be targeted for tuberculosis skin testing. Skin testing low risk populations will result in unnecessary testing and treatment because of false-positive test results.

High risk for developing TB disease is defined as:

- (1) recent infection with *Mycobacterium tuberculosis*,
- (2) the presence of clinical conditions that are associated with an increased risk of progression of LTBI to active TB (see **Appendix 1: Tables 1 and 2**) or
- (3) increased morbidity if progression to TB disease occurs.

Definition of a positive tuberculin skin test

Previous vaccination with BCG is not a contraindication to tuberculin skin testing. Because most persons who have received prior BCG vaccination are from high prevalence areas of the world, previous vaccination should be ignored when interpreting a tuberculin skin test.

- I. ≥ 5 mm of induration*
 - A. Persons known or suspected to have HIV infection.
 - B. Recent contacts to an active case of pulmonary or laryngeal TB.
 - C. Persons with an abnormal chest radiograph consistent with TB disease.
 - D. Immunosuppressed individuals (See page 3 **Indications for Treatment of LTBI -TB2 and TB4, VI-E**)
***Note:** The California Department of Corrections considers all inmates high risk, and therefore treats for latent infection all inmates 5mm.

II. ≥ 10 mm of induration

All persons except those in I. above

Note: The CDC recommends using a 15 mm cutoff for low risk reactors. However, in California, public health departments do not recognize this cutoff because California is a high incidence state and the prevalence of nontuberculous mycobacterial infections is lower than other regions of the United States.

III. Tuberculin skin test conversion

TST conversion is defined as an increase of at least 10 mm of induration from < 10 mm to ≥ 10 mm within two years from a documented negative to positive TST.

Example: a TST of 4 mm that increases in size to 14 mm or more in induration would be considered a skin test conversion.

In some cases, the exact size (in mm) of the previous tuberculin skin test may not be known. In such cases, skin test conversion is defined as a change from a negative to positive tuberculin skin test within a 2-year period.

Evaluation for TB Disease - Symptom review and chest radiography

- I. All persons who have a positive tuberculin skin test should undergo symptom review and have a chest radiograph.
 - A. If the radiograph is normal and the patient is asymptomatic, treatment of LTBI may be indicated (see **Appendix 2**).
 - B. If the radiograph is normal but the patient has a clinical presentation consistent with tuberculosis, further work-up is indicated and treatment of LTBI should be delayed until active tuberculosis has been ruled out.
- II. Bacteriologic studies should be obtained for all persons with an abnormal chest radiograph consistent with tuberculosis even when the radiographic abnormalities appear stable. If bacteriologic studies are obtained, treatment of LTBI should not be initiated until final culture results are available.

Definition of persons eligible for treatment of LTBI (TB2 and TB4)

The following classes of persons are eligible for treatment of LTBI if they have not received a prior course of treatment for active TB or LTBI. In some cases, individuals may require another course of therapy if they have been exposed as a close contact to an infectious case of TB and have HIV/AIDS or are otherwise immunosuppressed.

- I. TB2 - Tuberculosis infection, no disease:
Positive reaction to tuberculin skin test, negative bacteriologic studies (if done) and no clinical and/or radiographic evidence of tuberculosis.
- II. TB4 - Tuberculosis, no current disease:
 - A. History of previous episode(s) of tuberculosis, or
 - B. Abnormal*, but stable, radiographic findings in a person with a positive tuberculin skin test, negative bacteriologic studies, and no clinical and/or radiographic evidence of current disease.

*Abnormal refers to radiographs with parenchymal abnormalities consistent with TB. It does not refer to isolated calcified granulomas or apical pleural thickening

Indications for Treatment of LTBI - TB2 and TB4 (See Appendix 2)

Persons in the following categories including pregnant women, except when otherwise noted, should be treated if their tuberculin skin test is positive and they have not previously completed a course of therapy for tuberculosis or LTBI.

- I. Persons known or suspected to have HIV infection, regardless of age.
- II. Persons with an abnormal chest radiograph suggestive of tuberculosis and classified as a TB 4, regardless of age.
- III. Recent close contacts to active pulmonary or laryngeal TB, regardless of age.
- IV. Tuberculin skin test converters, regardless of age.
- V. Persons from countries with high TB rates but no other risk factors, except for pregnant women.
 - A. Recent arrivals to the USA (arrived within the past 3 years or less), regardless of age.
 - B. Remote arrivals to the USA (resided continuously in the USA for more than 3 years), and are **NOT OVER 35 YEARS OF AGE**.
- VI. Persons with the following conditions that have been associated with an increased risk of TB (See Appendix 1, Tables 1 and 2), regardless of age:
 - A. Injection drug use, regardless of HIV serostatus
 - B. Diabetes mellitus (especially insulin-dependent)
 - C. Silicosis
 - D. End-stage renal disease
 - E. Chronic immunosuppression
 1. Transplant recipients
 2. Prolonged corticosteroid therapy (15 mg/day for 1mo)
 3. Other immunosuppressive therapy
 - F. Hematological and reticuloendothelial diseases

- G. Malnutrition and clinical situations associated with rapid weight loss
 - 1. Cancer of the head and neck
 - 2. Intestinal bypass or gastrectomy
 - 3. Chronic malabsorption
 - 4. Low body weight (>10% below ideal body weight)
- VII. Children and adolescents < 18 years of age exposed to adults with any of the above high risk characteristics, except if pregnant.
- VIII. Residents and employees of the following high risk congregate settings: prison and jails, nursing homes, and other long-term facilities for the elderly, residential facilities for patients with AIDS, and homeless shelters; other homeless persons; employees of hospitals and other health care facilities **regardless of age.**
- IX. Persons with a positive tuberculin skin test not in the above categories who abuse alcohol, cocaine, and intravenously injected drugs who are tested and have LTBI **regardless of age.**
- X. All other
- XI. All persons who are tested and have LTBI and are **NOT OVER 35 YEARS OF AGE**, except for pregnant women.

Indications for Treatment of LTBI - TB1 (TB exposure but negative skin test) (See Appendix 2)

Close Contacts

In close contacts to infectious cases, the initial tuberculin skin test may be negative despite underlying infection with *M. tuberculosis* if the TST is placed before the contact has mounted an immune response to the tuberculin antigen. It takes 2-12 weeks after infection with *M. tuberculosis* to develop a positive TST reaction.

Close contacts (TB1) to an infectious case, who have a tuberculin skin test < 5 mm, should have a chest radiograph obtained, and once TB disease is excluded, should be started on therapy for LTBI regardless of age **IF:**

- I. Circumstances suggest a high probability of infection. For example, evaluation of other contacts with a similar degree of exposure demonstrates a high prevalence of infection, documented converters, or secondary cases.
- II. The contact is a child under 5 years of age, or is infected with HIV, or is otherwise immune-compromised.

For those individuals who are started on therapy with a TST < 5 mm, a repeat tuberculin skin test should be performed 10 to 12 weeks after contact with the infectious case has been broken, or the index case becomes non-infectious, to determine if the skin test has become positive. Decision on continuing therapy should be made once the result of repeat skin testing is available.

Note: In HIV infected contacts; treatment should be completed, regardless of the result of the repeat skin test.

Treatment Regimens for LTBI

(See **Appendix 3**, for intervals and duration, drug dosages, and treatment completion criteria)

The standard regimen is isoniazid (INH) as a single drug.

- I. INH alone:
 - A. 6 month regimen (minimum) for immune-competent adults. 9 month regimen if twice-weekly
 - B. 9 month regimen for children and adolescents (up to age 16 - 18)
 - C. 9 month regimen for HIV-infected persons or persons suspected of having HIV infection
 - D. 9 month regimen for TB 4 (See also **IV** below)

Alternative regimens for special circumstances.

- II. RIF and PZA for 2 months:

Approval from the TB Control Program is required before using this regimen.

This regimen is not to be used except in HIV infected persons who are at very high risk for tuberculosis and unlikely to take 6 – 9 months of INH. Particular caution is necessary in patients taking other medications associated with liver injury, and those with a history of alcoholism even if alcohol use is discontinued during treatment. Rifampin/pyrazinamide is contra-indicated for persons with underlying liver disease or for those who have had isoniazid-associated liver injury. Rifampin/pyrazinamide must be given by directly observed therapy (DOT).

- III. Rifampin alone for 6 months:

treat persons exposed to cases with mono-resistance to INH or intolerance to INH with 6 months of RIF. A 2-month regimen of RIF and PZA is not recommended.

- IV. INH and RIF (Rifamate) or RIF alone for 4 months for TB 4.

Although there have been no randomized studies to document the efficacy of this regimen in persons classified as a TB 4, there is a great deal of experience with this regimen in the public health sector. Give this regimen to TB suspects who have been started on treatment for TB but are later determined to be TB 4. The time for treatment as a suspect case should be included in the total 4 months recommended for treating LTBI.

- V. Rifabutin may be substituted for rifampin in the above regimens in situations where rifampin cannot be given such as in HIV-infected persons taking certain protease inhibitors or non-nucleoside reverse transcriptase inhibitors. Dosage adjustments may, however, be necessary. TB Control should be consulted before making this substitution.
- VI. Regimens for Contacts to Drug Resistant Cases

- A. INH mono-resistant source case

Refer to III above.

B. Multidrug resistant source case

Persons exposed to a multidrug resistant case of TB require consultation with TB Control for expert advice concerning appropriate treatment.

Daily vs. Intermittent Dosing

INH may be given daily or twice weekly when treating LTBI. When INH is given twice weekly it must be given by DOT and the length of therapy should be a minimum of 9 months.

Intermittent therapy should not be used with a 2 month RIF and PZA regimen except under an approved protocol from TBC.

A. Directly Observed Therapy

Directly observed therapy (DOT) for LTBI should be used in circumstances where the risk of nonadherence is judged to be high, the risk of progression to active disease is high, or when the treatment regimens are given intermittently. New short course regimens and intermittent dosing may make DOT more feasible.

Monitoring for Drug Toxicity and Adherence

I. Baseline Evaluation

A. Baseline laboratory testing is not routinely indicated for all persons at the start of treatment for LTBI. Such testing may, however, be considered on an individual basis. Persons with the following high-risk characteristics are required to have baseline laboratory testing:

1. HIV infection
2. History of, or at risk of, chronic liver disease
3. Alcoholism
4. Taking other hepatotoxic medications
5. All persons over 35 years of age
6. Pregnant women and those in the immediate post-partum period (3 – 6 months)

B. The baseline laboratory tests will depend on which drug regimen is being used.

1. Isoniazid-containing regimen - In persons taking isoniazid, baseline measurements of serum AST or ALT and bilirubin are indicated.
2. Rifampin (or rifabutin) -containing regimen - In persons taking a rifamycin, baseline measurements of complete blood count and platelets are recommended, in addition to liver function tests.
3. Pyrazinamide-containing regimen - same as rifampin-containing regimen. A baseline uric acid level is not necessary unless the patient has a history of gout.

II. Evaluation During Treatment

A. Clinical Evaluation - Patients being treated for LTBI should receive a clinical evaluation at least monthly, regardless of the regimen used. The evaluation should include careful questioning of the patient about side effects associated with the medications, particularly hepatitis (e.g., anorexia, malaise, abdominal pain, fever, nausea, vomiting, dark urine, icterus). In addition, the patient should be asked about adherence and educated about the possible side effects of the medications.

No more than a one-month supply of medication is to be dispensed at a time.

- B. Rifampin and pyrazinamide containing regimens require more frequent monitoring. Liver function studies including a serum aminotransferase (AT) and bilirubin must be done at baseline, weeks 2, 4, and 6 of therapy. Asymptomatic serum AT increases are expected but do not require that treatment be stopped unless the AT level is greater than three times the upper limit of normal range in which case the regimen should not be resumed. Treatment should also be stopped and not resumed if any of the following findings occur: AT greater than normal range accompanied by symptoms of hepatitis, or a serum bilirubin greater than normal whether symptoms are present or not. Rifampin/pyrazinamide must be given by DOT.
- C. Routine laboratory monitoring during treatment of LTBI is indicated for those whose baseline liver function are abnormal, for persons at high risk of hepatic disease, or persons with symptoms of hepatitis. The frequency of this monitoring will vary depending on the person's risk of liver disease and the severity of the liver function test abnormalities.

Note: Pregnant women and those in the immediate post-partum period (within 3 - 6 months of delivery) *must* have repeat liver function tests measured monthly.

III. When To Stop Medications Due to Drug-induced Hepatitis

Medications should be stopped if the transaminase levels exceed **3** times the upper limit of normal. Medication should be held pending further clinical and laboratory evaluation.

Completion of Therapy

Completion of therapy should be based on the total number of doses administered not duration of therapy. If treatment is interrupted the recommended number of doses of the regimen should be provided within a certain maximum time period (See **Appendix 3**). The entire regimen should be restarted if interruptions were frequent or prolonged enough to preclude completion of doses in the time frames specified. When therapy is restarted after an interruption of more than 2 months, a medical examination to exclude active disease is indicated.

The standard in LAC when closing a patient being treated for LTBI to the TB Registry is to include the total number of medication doses received over a specific period of time.

Note: No set of standards can cover all individual treatment situations that can and will arise. Thus, when questions on individual situations not covered by these standards do arise, consult with LAC TB Control Program.

These standards have been approved and are in effect as of February 2001 and revised October 2001:

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VII. Suggested Readings

1. American Academy of Pediatrics. 2000. Tuberculosis. *In* Red Book: Report of the Committee on Infectious Diseases, 25th ed. American Academy of Pediatrics, Elk Grove Village IL.
2. American Thoracic Society / Centers for Disease Control and Prevention. Treatment of tuberculosis and tuberculosis infection in adults and children. *Am J Respir Crit Care Med* 1994; 149: 1359-1374.
3. American Thoracic Society / Centers for Disease Control and Prevention. Targeted skin testing and treatment of latent tuberculosis infection. *Am J Respir Crit Care Med.* 2000 161: S221-S247.
4. American Thoracic Society / Centers for Disease Control and Prevention. Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med* 2000; 161:1376-1395.
5. Centers for Disease Control and Prevention. Notice to readers. Updated guidelines for the use of rifabutin or rifampin for the treatment and prevention of tuberculosis among HIV-infected patients taking protease inhibitors or nonnucleoside reverse transcriptase inhibitors. *MMWR* 2000; 49:185-189.
6. Centers for Disease Control and Prevention. Update: Fatal and Severe Liver Injuries Associated With Rifampin and Pyrazinamide for Latent Tuberculosis Infection, and Revisions in American Thoracic Society/CDC Recommendations-United States, 2001 *MMWR* 2001; 50(34);733-5.
7. Zuber PLF, McKenna MT, Binkin NJ, Onorato IM, Castro KG. Long-term risk of tuberculosis among foreign-born persons in the United States. *J.A.M.A.* 1997; 278:304-307.

Appendix 1

High Risk Populations

Table 1. Incidence of Active TB in Persons with a Positive TST by Selected Factors

Risk Factor	TB Cases/1000 person-years
Infection > 2 years past	1.6
Infection < 1 year past	12.9
HIV Infection	35.0-162.0
Injection Drug Use	
HIV seropositive	76.0
HIV seronegative or unknown	10.0
Silicosis	68
Radiographic findings consistent with old TB	2.0-13.6

Source: American Thoracic Society/Centers for Disease Control and Prevention, 2000

Table 2. Certain medical conditions associated with an increased risk of developing TB

Medical Condition	Relative Risk
Solid organ transplant	
Renal	37
Cardiac	20-74
Jejunioileal bypass	27-63
Silicosis	30
Chronic Renal Failure/Hemodialysis	10.0-25.3
Carcinoma of head and neck	16
Gastrectomy	2-5
Diabetes mellitus	2.0-4.1

Source: American Thoracic Society/Centers for Disease Control and Prevention, 2000

Appendix 2

CANDIDATES FOR TREATMENT OF LATENT TUBERCULOSIS INFECTION (LTBI) (adapted from Charles P. Felton National TB Center)			
Category of person tested	TST <5 mm	TST, 5 mm	TST, 10 mm
(1) Recent Contact to TB Case¹			
1. Child <5 years and recent contact ²	TREAT	TREAT	TREAT
2. HIV-infected and recent contact ²	TREAT	TREAT	TREAT
3. Immunosuppressed and recent contact ²	TREAT	TREAT	TREAT
4. Other recent contact of TB case	Do Not Treat	TREAT	TREAT
(2) No Recent Contact to TB Case			
1. Fibrotic changes on chest X-ray ³	Do Not Treat	TREAT	TREAT
2. HIV-infected	Do Not Treat	TREAT	TREAT
3. Injection drug user with unknown HIV status	Do Not Treat	TREAT	TREAT
4. Other immunosuppressed persons ⁴	Do Not Treat	TREAT	TREAT
5. Foreign-born persons from endemic country ⁵	Do Not Treat	Do Not Treat	TREAT
6. Injection drug user known to be HIV negative	Do Not Treat	Do Not Treat	TREAT
7. Resident/Employee institutional setting ⁶	Do Not Treat	Do Not Treat	TREAT
8. Mycobacteria lab personnel	Do Not Treat	Do Not Treat	TREAT
9. High-Risk clinical conditions ⁷	Do Not Treat	Do Not Treat	TREAT
10. Children < 18 years of age exposed to adults at high risk	Do Not Treat	Do Not Treat	TREAT
11. Other persons depending on local epidemiology and resources	Do Not Treat	Do Not Treat	TREAT

Note: If a person meets more than one criteria for treatment, the lower TST cut point for therapy should be used (i.e. an immigrant from a TB endemic country who has fibrotic changes on chest radiograph should be treated if the TST is ≥ 5 mm induration)

¹Recent contacts to active case of pulmonary or laryngeal TB.

²Recent contacts who are initially TST-negative should have a TST repeated 8-12 weeks after last exposure to TB case (see Text). Treatment can usually be discontinued after negative second TST in children. HIV infected adults and children, however, should receive full course of therapy regardless of TST result.

³Abnormal, stable, radiographic findings (parenchymal abnormalities consistent with TB, not isolated calcified granuloma or apical pleural thickening). Bacteriologic studies should be obtained for all persons with an abnormal chest radiograph consistent with TB even when the radiographic abnormalities appear stable. When bacteriologic studies are obtained, treatment of LTBI should not be initiated until final culture results are available.

⁴Transplant recipients, prolonged corticosteroid therapy (15 mg/day for 1 month), other immunosuppressive therapy

⁵Persons who have resided in the U.S. for over 3 years should receive treatment if they are not over 35 years of age.

⁶Residents and employees of the following high risk congregate settings: prisons and jails*, nursing homes and other long-term facilities for the elderly, residential facilities for patients with AIDS, homeless shelters; other homeless persons; employees of hospitals and health care facilities.

*The California Department of Corrections considers all inmates high risk, and therefore treats for latent infection all inmates with a reaction ≥ 5 mm.

⁷Silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g. leukemias and lymphomas), other specific malignancies (e.g. carcinoma of the head and neck or lung), weight loss of 10% of ideal body weight, gastrectomy, jejunioileal bypass.

Pregnancy: Treat during pregnancy if either HIV-infected or recent *M.tb* infection.

Appendix 3

Recommended Drug Treatment Regimens For Treatment of LTBI

Drug	Interval & Duration	Adult Dose (max)	Pediatric Dose (max)	Criteria for Completion	Monitoring	Comments
INH	Daily for 6 mos	5 mg/kg (300 mg)		180 doses within 9 mos	Clinical monitoring monthly. Liver function tests ¹ at baseline in selected cases ² and repeat measurements if baseline tests are abnormal, patient is at high risk for adverse reactions, or patient has symptoms of hepatitis.	Preferred regimen for all immune-competent adults.
	Twice-weekly for 9 mos	15 mg/kg (900 mg)		76 doses within 12 mos		Alternate regimen for adults. DOT must be used with twice-weekly dosing
INH	Daily for 9 mos	5 mg/kg (300 mg)	10-20 mg/kg (300 mg)	270 doses within 12 mos		Preferred for children and HIV-infected adults. In HIV-infected patients, INH may be administered concurrently with NRTIs, protease inhibitors, or NNRTIs
	Twice-weekly for 9 mos	15 mg/kg (900 mg)	20-40 mg/kg (900 mg)	76 doses within 12 mos		Alternate regimen for children and HIV-infected. DOT must be used with twice-weekly dosing
RIF plus PZA	Daily for 2 mos	RIF 10mg/kg (600 mg) PZA 15-20 mg/kg (2.0 g)	nr	60 doses within 3 mos	Clinical monitoring at baseline, weeks 2, 4, and 6. Liver function tests ¹ at baseline and repeat measurements if baseline results are abnormal or patient has symptoms of adverse reactions. Requires TB Control approval. Medications must be given by DOT.	Alternate regimen for HIV-infected adults unlikely to take 6-9 mos of INH. In HIV-infected patients, certain protease inhibitors or NNRTIs should not be administered concurrently with RIF; an alternative is rifabutin 300 mg daily.
RIF	Daily for 6 mos.	10 mg/kg (600 mg)	10-20 mg/kg (600 mg)	120 doses within 9 mos	Clinical monthly monitoring Complete blood count, platelets, and liver function tests ¹ at baseline in selected cases ² and repeated measurements if baseline results are abnormal or patient has symptoms of adverse reactions	For persons exposed to INH resistant, RIF susceptible TB and those who cannot tolerate INH.
INH plus RIF	Daily for 4 mos.	INH 5 mg/kg (300 mg) RIF 10mg/kg (600 mg)		120 doses within 6 mos	See INH and RIF	Alternate regimen for TB Class 4 (history of previous TB or abnormal but stable radiographic findings without evidence of active TB.)

Abbreviations: INH = isoniazid, RIF = rifampin, PZA = pyrazinamide, NRTIs = nucleoside reverse transcriptase inhibitors, NNRTIs = non-nucleoside reverse transcriptase inhibitors, DOT = directly observed therapy, mos. = months, nr = not recommended. **Pregnancy:** INH regimens preferred for pregnant women. Some experts would use RIF plus PZA as an alternate regimen in HIV-infected pregnant women. PZA should be avoided during the first trimester. **MDR-TB exposure:** For persons who are likely to be infected with INH and RIF (multi-drug) resistant TB and at high risk of reactivation, PZA and ethambutol or PZA and a fluoroquinolone are recommended depending on the sensitivities of the M. tb isolate. (Consult expert.)

¹ AST or ALT and serum bilirubin

² HIV Infection, history of liver disease, alcoholism, and pregnancy

Appendix 4

Definitions and Abbreviations

1. LTBI Latent tuberculosis infection
2. TB1 Tuberculosis exposure--no evidence of infection
History of exposure
Negative reaction to tuberculin skin test
3. TB2 Tuberculosis infection--no disease
Positive reaction to tuberculin skin test
Negative bacteriologic studies (if done)
No clinical, bacteriological, or radiographic evidence of current disease
4. TB3 Tuberculosis disease--clinically active
Mycobacterium tuberculosis cultured (if done)
Clinical, bacteriological, or radiographic evidence of current disease
5. TB4 Tuberculosis--not clinically active
History of episode(s) of tuberculosis, or
Abnormal but stable radiographic findings
Positive reaction to the tuberculin skin test
Negative bacteriologic studies (if done), and
No clinical or radiographic evidence of current disease
6. TB5 Tuberculosis disease suspected
Diagnosis pending
7. CDC Centers for Disease Control and Prevention
8. TST Tuberculin skin test
9. LAC Los Angeles County
10. DHS Department of Health Services
11. TBC Tuberculosis Control Program
12. DOT Directly observed therapy
13. ATS American Thoracic Society