State of California—Health and Human Services Agency
Department of Health Care Services

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DATE: August 1, 2011

CHDP Provider Information Notice No.: 11-04 Revised

TO: ALL CHILD HEALTH AND DISABILITY PREVENTION (CHDP) PROGRAM PROVIDERS AND MEDI-CAL MANAGED CARE PLANS

SUBJECT: CHDP HEALTH ASSESSMENT GUIDELINES (HAG) REVISIONS: SECTION 73, TUBERCULOSIS

The purpose of this CHDP Provider Information Notice No. 11 – 04 is to inform CHDP providers of the revised section of the CHDP Health Assessment Guideline (HAG), Section 73, formerly Section 703, **Tuberculosis (TB)**. This revised HAG reflects changes in the policies of the American Academy of Pediatrics (AAP), Centers for Disease Control (CDC), and the California Department of Public Health (CDPH) Tuberculosis Control Branch since the release of the previous TB HAG in 1997. These changes include:

- Implementation of Targeted TB skin testing for all children, including:
  - Implementation of mandatory TB Risk Assessment Screening;
  - Table 73.1 Definitions of Positive Tuberculin Skin Test (TST) Results in Children and Adolescents
  - Links to up-to-date patient teaching materials on TB;
  - A discussion about the use of Interferon Gamma Release Assays (IGRAs), a blood test that was recently approved by the CDC for use in children as young as 5 years. This is **not** a CHDP–covered benefit, but can be reimbursed by Medi-Cal and Healthy Families for their beneficiaries.
  - Table 73.2 Pediatric TB Risk Assessment Questionnaire;
  - A Sample Questionnaire that may be used in provider offices.

This version of the TB Health Assessment Guideline includes modified versions of the TB Risk Assessment Questionnaire and the Sample Questionnaire.

Your continuing participation in the CHDP Program is greatly appreciated. If you have any questions, please contact your local CHDP Program.

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Enclosure

TUBERCULOSIS

RATIONALE

Tuberculosis (TB) remains a significant public health problem in California. In 2009, 2,472 cases of TB disease were reported in California; 71 of the reported cases were in children under 5 years of age. While the number and rate of TB cases in this group has not changed significantly since 2005, the rate of decrease has slowed. TB rates among children under 5 years of age are 5-11 times greater among Asian/Pacific Islanders, Hispanics, and Black non-Hispanics compared to White non-Hispanics[1]. There is significant regional variation in TB incidence, with the majority of TB cases in large counties and in areas with large immigrant populations.

TB infection may manifest as TB disease or Latent Tuberculosis Infection (LTBI). LTBI is a condition in which a person is infected with *M. tuberculosis*, does not currently have active TB disease, but is at risk of progression to active disease. Individuals with LTBI are asymptomatic and not infectious. Identifying children with LTBI in order to intervene with treatment is necessary to prevent future disease. It is also important for case identification, as most children under age five years with LTBI have recently acquired the infection from a person with active TB disease.

The most important steps to reducing the number of children with TB disease are prompt and thorough contact investigation of persons with known or suspected TB and active monitoring of infected contacts until completion of treatment.

The CHDP Program supports the recommendations of the Tuberculosis Control Branch for tuberculosis screening. The Tuberculosis Control Branch of the California Department of Public Health recommends screening two groups of individuals: (1) those who are at increased risk of contracting TB (as determined by responses to the TB Risk Assessment Questionnaire – see Table 73.2), and (2) those at increased risk of progression from LTBI to active disease based on coexisting medical conditions.[2]

The Mantoux Tuberculin Skin Test (TST), using purified protein derivative (PPD), is the only method currently approved for reimbursement by CHDP for identifying children infected with *M. tuberculosis*. The tuberculin skin test is preferred for routine targeted testing for latent TB. infection.

1 http://www.cdph.ca.gov/programs/tb/Documents/TBCB-WorldTBDay2010-combined.pdf

2 American Academy of Pediatrics. Tuberculosis. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS, eds. Red book: 2009 report of the Committee on Infectious Disease. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics, 2009:680–701.

SCREENING REQUIREMENTS

- Assess all children for risk of exposure to tuberculosis at each health assessment visit. Questions for determining risk of LTBI in children in the U.S. may be found in Table 73.2: Pediatric TB Risk Assessment Questionnaire.

- For children who are at increased risk of acquiring LTBI (including those with a positive Risk Assessment Questionnaire and incarcerated adolescents), test for TB.

- For children who are more likely to progress to active TB if exposed (children with HIV, organ transplant, TNF-alpha inhibitors, or other condition associated with significant immunosuppression), test for TB.

- When tuberculosis testing is indicated, the clinician may place a TST.

- The *only* contraindication to the TST is history of a severe reaction (e.g., necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST[3].

- Administer the TST as described in Basics of TST Administration (see page 73-5).

- Read the TST 48 to 72 hours after placement and record the results in millimeters (mm) of induration, not erythema. Measure the diameter of the induration transversely to the long axis of the forearm. Trained personnel, not parents, must read the skin test. See Table 73.1.

- If the child fails to return for the scheduled reading:
  1. **Only** a positive reaction may still be measured up to one week after testing.
  2. Repeat the TST if no positive reaction can be measured when the child does return.

- When questions arise about the reading of a TST, consult your local health department TB Control program.

- Testing for tuberculosis is ***not*** a universal requirement for school entry in California. However, California law allows local health departments to require TB testing for school entry based on local epidemiology.[4] Check with your local health department for the local policy.

3 http://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm
4 California Health and Safety Code. § 121485 - 121520.

Table 73.1 DEFINITIONS 0F POSITIVE TST RESULTS IN CHILDREN AND ADOLESCENTS [5]

Reaction Size*	Definition of Mantoux skin test (5 TU PPD)
5-9 mm induration	**Positive** Children are considered positive if they are in the following category: Recent contacts with infectious TB cases. HIV infected children and adolescents. Children and adolescents with fibrotic changes on chest radiograph consistent with prior TB. Organ transplant recipients. Children and adolescents who are immuno-suppressed for other reasons.
≥ 10 mm induration	POSITIVE FOR ALL CHILDREN AND ADOLESCENTS: Children or adolescents at increased risk of disseminated disease: 1. Those < 4 years of age 2. Those with concomitant medical conditions. Children or adolescents with increased risk of exposure to cases of TB disease: 1. Those born in a country with high prevalence of TB cases. 2. Those who travel to a country with a high prevalence of TB cases. 3. Those with parents born in a country with a high prevalence of TB cases. 4. Those who are frequently exposed to adults with risk factors for TB disease.

*Interpretation of the skin test should be made without regard to previous Bacillus of Calmette-Guérin (BCG) vaccine administration.

Note: The Centers for Disease Control and Prevention classification of positive reactions includes a category 15 mm for all other children, (e.g., low risk groups). This classification is not recognized by public health departments in California because PPD cross reactivity to other mycobacterium is low and TB prevalence rates are higher due to a greater number of individuals in high risk groups compared to the rest of the United States. 10 mm is considered positive, except in close contacts, HIV positive individuals, and those with abnormal x-rays, in which 5 mm is positive.

5 Modified from American Academy of Pediatrics. *Red Book: 2009 Report of the Committee on Infectious Diseases.* 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009:680-708.

CONSIDERATIONS FOR REFERRAL, TREATMENT, AND/OR FOLLOW-UP

- Refer any child for diagnosis and treatment who has symptoms consistent with active TB disease regardless of the test results.

- Evaluate all children with positive results and provide or refer for a medical evaluation, chest x-ray, and any other laboratory studies needed for the diagnosis of TB disease.

- Report to the local health department any confirmed or suspected case of TB disease within one day of identification (California Code of Regulations, Title 17, Section 2500). Contact your local health department for specific instructions about reporting children with latent TB infection, or converters, and for additional information regarding therapy.

- If TB disease is not found, place children and adolescents with positive TST on therapy, unless medically contraindicated.

- Consult with your local health department Tuberculosis Control Program for guidance on need for confirmatory IGRA blood test (see below for a discussion of IGRAs) to rule out a false positive TST in children and youth aged 5 – 21 years, as well as the most effective treatment regimen. Treatment with Isoniazid (INH) has been shown to be very effective in preventing clinical disease in most cases. Efficacy is directly related to the length of treatment and the extent of compliance with the regimen.

- Close contacts of persons with active TB disease are candidates for LTBI therapy if:

    1. TST negative children are less than 5 years of age
    2. Any immunosuppressed persons of any age
    3. Repeat TST done 8 weeks after the last contact when the TB case was infectious. Exceptions to stopping treatment if the 8 week TST is negative include infants, in whom a negative TST is not reliable until after 6 months of age, or severely immunosuppressed children, in whom continuation of LTBI treatment for 6-9 months should be considered even if repeat TST is negative.

- Refer all household contacts of persons being treated for active TB disease to the local health department for follow-up or contact tracing.

BACILLUS of CALMETTE-GUÉRIN (BCG) VACCINATION

Many developing countries still use BCG as part of their TB control programs, especially for infants, to prevent the development of disseminated or meningeal disease. There is no reliable way to distinguish TST reactions caused by BCG vaccination from those caused by natural infections. Because many BCG - vaccinated persons come from areas of the world where TB transmission is common, testing for tuberculosis should be done, preferably with an IGRA blood test. If a BCG-vaccinated child over 5 years has a positive TST result, it should be confirmed by IGRA testing before a diagnosis of infection with *M. tuberculosis* is made.

BASICS OF TST ADMINISTRATION

The Mantoux tuberculin skin test (TST) is the only test approved for screening children under 5 years of age. The antigen is aspirated into a disposable plastic syringe with a No. 26 gauge, short-bevel needle no more than one (1) hour before use. Purified protein derivative containing five tuberculin units (5 TU) in 0.1 ml is injected intradermally on the volar aspect of the forearm to produce a six to ten mm wheal. The TST may be placed on the same day that a Measles-containing vaccine is given. If not placed on the same day, it is recommended that you wait four to six weeks before placing a Mantoux tuberculin skin test.[6]

LOCAL HEALTH DEPARTMENT RESOURCES

Your local health department Tuberculosis Control Program staff are available for consultation on all aspects of TB prevention and treatment, including the training of staff to perform, read, and record TB Mantoux tests. They can provide information about TB trends in your community, provide laboratory services, and assist with arrangements for directly observed therapy (DOT) and the identification and examination of source cases and contacts.

Patient teaching materials are available in English and Spanish from the Centers for Disease Control (CDC) at: http://www.cdc.gov/tb/publications/factsheets/testing.htm.

6 http://www.cdc.gov/vaccines/vpd-vac/faqs-nipinfo-general.htm#a6 : Vaccines and PPD Testing.

INTERFERON GAMMA RELEASE ASSAYS

Interferon Gamma Release Assays (IGRAs), such as the *QuantiFERON -TB Gold* (QFT-G), *QuantiFERON -TB Gold-In Tube (*QFT-GIT), and T-Spot® were approved by the CDC, for testing in those 5 years and older, in June, 2010.[7] Medi-Cal updated its guidelines and instructions for IGRA testing effective October 2010 to incorporate these revised recommendations. (See the Medi-Cal Provider Manual for billing instructions).[8]

IGRAs are acceptable alternatives for targeted testing for latent TB infection, and may be preferred in some settings. There are a number of advantages to IGRA testing. Testing requires only a single patient visit to draw a blood sample and does not boost responses measured by subsequent tests (which can occur with TSTs). In addition, test results can be available within 24 hours, are not subject to the reader bias that can occur with the TST, and are not affected by prior BCG (Bacille Calmette-Guerin) vaccination.[9] CDC recommends the use of IGRA testing for:

- Populations with low compliance rates for returning to have a TST read.
- Evaluation of patients who have received BCG (as a vaccine or for cancer therapy).

Arrangements for IGRA testing should be made prior to blood collection to ensure that the blood specimen is collected in the proper tubes, and that testing can be performed within the required timeframe. Your local health department TB Control program should have this information.

The CHDP Program does not currently reimburse for IGRA testing.

7 Centers for Disease Control and Prevention. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection — United States, 2010. MMWR 2010;59(No. RR-#5).(http://www.cdc.gov/mmwr/pdf/rr/rr5905.pdf)
8 http://files.medi-cal.ca.gov/pubsdoco/publications/Masters-MTP/Part2/pathimmun_m00o03.doc
9 http://www.cdc.gov/tb/publications/factsheets/testing/QFT.pdf

Table 73.2 PEDIATRIC TB RISK ASSESSMENT QUESTIONNAIRE [10]

If there is a yes response to any of the risk assessment questions, a TB skin test must be placed

Question*	Follow-up
1. ***Was your child born in a high risk region(including Africa, Asia, Eastern Europe or Latin America)?*** If yes, this question should be followed by: • Where were you and/or your child born?	If the parent or child was born in Africa, Asia, Latin America, or Eastern Europe, a TST should be placed.
2. ***Has your child ever traveled to a high risk country for more than 1 week?*** If yes, this question should be followed by questions to determine: • Where did your child travel? • How long was your child outside the United States?	If the child stayed with friends or family members in Africa, Asia, Latin America, or Eastern Europe for 1 week cumulatively, a TST should be placed.
3. Has a family member or contact had tuberculosis disease? If yes, this question should be followed by: • Did the person have TB disease or LTBI? • When did the exposure occur? and • What was the nature of the contact?	If confirmed that the child has been exposed to an individual with suspected or known TB disease, a TST should be placed. If it is determined that the child had contact with an individual with TB disease, notify the local health department per local reporting guidelines.
4. Has a family member or close contact had a positive Tuberculin skin test? If yes, this question should be followed by: • Did the person have TB disease or LTBI? • When did the exposure occur? and • What was the nature of the contact?	If confirmed that the child has close contact with an individual with a positive skin test, a TST should be placed.

* Adolescents can be asked these questions directly.

10 Adapted from: ***Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents***. Pediatric Tuberculosis Collaborative Group. *Pediatrics* 2004;114;1175-1201, p. 1178. DOI: 10.1542/peds.2004-0809. http://pediatrics.aappublications.org/cgi/reprint/114/4/S2/1175

Today's Date: _____

Name of Child: _____ Date of Birth: _____

PEDIATRIC TB RISK ASSESSMENT QUESTIONNAIRE

1. ***Was your child born in a high risk region?**** **Yes ☐ No ☐**
2. ***Has your child ever traveled to a high risk country for more than 1 week?*** **Yes ☐ No ☐**
3. Has a family member or contact had tuberculosis disease? **Yes ☐ No ☐**
4. Has a family member or close contact had a positive Tuberculin skin test? **Yes ☐ No ☐**

- High Risk Region = any country in Africa, Asia, Central America, South America, or Eastern Europe