of Tennessee

Policy

Reimbursement Policy

Testing for Diagnosis of Active or Latent Tuberculosis

I. Policy Description

Infection by *Mycobacterium tuberculosis* (Mtb) results in a wide range of clinical presentations dependent upon the site of infection from classic signs and symptoms of pulmonary disease (cough greater than two to three weeks' duration, lymphadenopathy, fevers, night sweats, weight loss) to silent infection with a complete absence of signs or symptoms.[1]

Culture of Mtb is the gold standard for diagnosis as it is the most sensitive and provides an isolate for drug susceptibility testing and species identification.[2] Nucleic acid amplification tests (NAAT) use polymerase chain reactions (PCR) to enable sensitive detection and identification of low-density infections.[3] Interferon-gamma release assays (IGRAs) are blood tests of cell-mediated immune response which measure T-cell release of interferon (IFN)-gamma following stimulation by specific antigens such as *Mycobacterium tuberculosis* antigens[1,4] used to detect a cellular immune response to *M. tuberculosis* which would indicate latent tuberculosis infection (LTBI).[5]

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) To diagnose or screen for latent tuberculosis (TB) infection, an interferon gamma release assay (IGRA) **MEETS COVERAGE CRITERIA** in:
   a) Individuals who are at risk for infection with *Mycobacterium tuberculosis* (Mtb).
   b) Individuals who are unlikely to be infected with Mtb when screening is obliged by law.
2) For all suspected TB infections, the following tests **MEET COVERAGE CRITERIA**:
   a) Acid fast bacilli (AFB) smear/stain.
   b) Culture and culture-based drug susceptibility testing of *Mycobacteria* spp.

c) Qualitative nucleic acid amplification testing (NAAT) for *Mycobacteria* spp., *M. tuberculosis,* and *M. avium* complex.

3) For individuals whose sputum is AFB smear positive or NAAT positive, molecular-based drug susceptibility testing **MEETS COVERAGE CRITERIA** when **one** of the following criteria is met:

a) The individual has been treated for TB in the past.

b) The individual was born in or has lived for at least 1 year in a foreign country with at least a moderate TB incidence (≥20 per 100, 000) or a high primary multi-drug resistant (MDR)-TB prevalence (≥2%).

c) The individual is a contact of an individual with MDR-TB.

d) The individual is HIV infected.

4) Repeat drug susceptibility testing **MEETS COVERAGE CRITERIA** in **any** of the following situations:

a) For individuals whose sputum cultures remain positive after 3 months of treatment.

b) When there is bacteriological reversion from negative to positive.

5) For individuals with pleural effusion, pericardial effusion, or ascites and suspected TB infection, cell counts, protein, glucose, and lactate dehydrogenase (LDH) concentrations of cerebrospinal, pleural, peritoneal, pericardial, and other fluids **MEETS COVERAGE CRITERIA**.

6) In HIV-infected individuals with CD4 cell counts ≤100 cells/microL who have signs and symptoms of tuberculosis, urine-based detection of mycobacterial cell wall glycolipid lipoarabinomannan (LAM) **MEETS COVERAGE CRITERIA**.

7) For individuals with active tuberculosis, IGRA **DOES NOT MEET COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

8) Quantitative nucleic acid testing for *Mycobacterium* spp, *M. tuberculosis*, and *M. avium* complex **DOES NOT MEET COVERAGE CRITERIA**.

9) Whole genome sequencing of *Mycobacterium* spp. for the detection of drug resistance **DOES NOT MEET COVERAGE CRITERIA**.

10) Genotyping of *Mycobacterium* spp. **DOES NOT MEET COVERAGE CRITERIA**.

11) Testing of adenosine deaminase (ADA) and interferon-gamma (IFN- γ) levels in cerebrospinal, pleural, peritoneal, pericardial, and other fluids for the diagnosis of extrapulmonary TB **DOES NOT MEET COVERAGE CRITERIA**.

12) Testing of serum protein biomarkers or panels of biomarkers for the detection and diagnosis of TB **DOES NOT MEET COVERAGE CRITERIA**.

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
81099	Unlisted urinalysis procedure
81425	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis
81426	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (e.g., parents, siblings) (List separately in addition to code for primary procedure
81479	Unlisted molecular pathology procedure
82945	Glucose, body fluid, other than blood
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified
83615	Lactate dehydrogenase (LD), (LDH);

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CPT	Code Description
84157	Protein, total, except by refractometry; other source (e.g., synovial fluid, cerebrospinal fluid)
84311	Spectrophotometry, analyte not elsewhere specified
86480	Tuberculosis test, cell mediated immunity antigen response measurement; gamma interferon
86481	Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon-producing T-cells in cell suspension
87070	Culture, bacterial; any other source except urine, blood, or stool, aerobic, with isolation and presumptive identification of isolates
87077	Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate
87116	Culture, tubercle, or other acid-fast bacilli (e.g., TB, AFB, mycobacteria) any source, with isolation and presumptive identification of isolates
87150	Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed
87153	Culture, typing; identification by nucleic acid sequencing method, each isolate (e.g., sequencing of the 16S rRNA gene)
87181	Susceptibility studies, antimicrobial agent; agar dilution method, per agent (e.g., antibiotic gradient strip)
87184	Susceptibility studies, antimicrobial agent; disk method, per plate (12 or fewer agents)
87185	Susceptibility studies, antimicrobial agent; enzyme detection (e.g., beta lactamase), per enzyme
87186	Susceptibility studies, antimicrobial agent; microdilution or agar dilution (minimum inhibitory concentration [MIC] or breakpoint), each multi-antimicrobial, per plate
87187	Susceptibility studies, antimicrobial agent; microdilution or agar dilution, minimum lethal concentration (MLC), each plate (List separately in addition to code for primary procedure)
87188	Susceptibility studies, antimicrobial agent; macrobroth dilution method, each agent
87190	Susceptibility studies, antimicrobial agent; mycobacteria, proportion method, each agent
87206	Smear, primary source with interpretation; fluorescent and/or acid-fast stain for bacteria, fungi, parasites, viruses, or cell types
87551	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria species, amplified probe technique
87552	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria species, quantification

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CPT	Code Description
87556	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria tuberculosis, amplified probe technique
87557	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria tuberculosis, quantification
87561	Infectious agent detection by nucleic acid (DNA or RNA); mycobacteria avium-intracellulare, amplified probe technique
87562	Infectious agent detection by nucleic acid (DNA or RNA); mycobacteria avium-intracellulare, quantification
87564	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacterium tuberculosis, rifampin resistance, amplified probe technique
0574U	Mycobacterium tuberculosis, culture filtrate protein–10-kDa (CFP-10), serum or plasma, liquid chromatography mass spectrometry (LC-MS) Proprietary test: NanoDetect-TB™ Lab/Manufacturer: NanoPin Technologies, Inc

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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VI. Revision History

Revision Date	Summary of Changes
09/04/2025	Reviewed and Updated: Updated background, guidelines, and evidence-based scientific references. Literature review necessitated the following changes in coverage criteria: Direct probe testing is no longer available. This results in removal of CC3 and qualitative NAAT testing becomes CC2.c.: "c) Qualitative nucleic acid amplification testing (NAAT) for Mycobacteria spp., M. tuberculosis, and M. avium complex."

	Former CC4, now CC3, replaced "Hologic Amplified MTD" with "NAAT" for clarity. Removed CC9. With removal of direct probes, there is no situation in which two types of NAAT would be allowed, making CC9 redundant. Former CC10, now CC8 updated "M. avium intracellulare" to "M. avium complex" to align with updated naming convention Removed CPT code 87149, 87550, 87555, 87560
06/04/2025	Off-cycle coding modification: Added CPT code 0574U (effective date 7/1/2025)
12/04/2024	Off-cycle coding modification: Added CPT code 87564 (effective date 1/1/2025)