|  |
| --- |
| Data Collection Form—Final**Report of Verified Case of Tuberculosis (RVCT) – 10/29/2019** |

# Administrative Information

1. **Date Reported:** 🞏🞏/🞏🞏/🞏🞏🞏🞏 **Date the health department first thought that the patient may have TB or date health department received written or verbal notification from a healthcare provider that a patient might have TB.**
2. **Date Counted Do not complete 2a and 2b at this time (central office responsibility)**
	1. MMWR Week:🞏🞏
	2. MMWR Year: 🞏🞏🞏🞏
3. **State Case Number:**🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 **Central Office will assign**
4. **Local Case Number:** 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 **Central Office will assign**
5. **Case Already Counted by Another Reporting Area?** **\*\*NEW VARIABLE\*\***

**Do not complete #5 at this time (central office responsibility)**

\_\_\_Yes, another U.S. reporting area (State case number from other area:
 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏)

\_\_\_Yes, another country (Specify country: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

\_\_\_No

# Demographics and Initial Evaluation

1. **Reporting Address**
	1. City: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	2. Is the Patient’s Residence within City Limits?

\_\_\_Yes

\_\_\_No

\_\_\_Unknown

* 1. County: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	2. ZIP Code: 🞏🞏🞏🞏🞏-🞏🞏🞏🞏
	3. Census Tract (11-digit GEOID): 🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏 **Do not complete**
1. **Date of Birth**: 🞏🞏/🞏🞏/🞏🞏🞏🞏
2. **Sex at Birth**

\_\_\_Male **The biological sex recorded for the patient at birth was male**

\_\_\_Female **The recorded biological sex recorded for the patient at birth was female**

If Female, Was Patient Pregnant **at Time of Diagnostic Evaluation**? **Per Nursing protocol 3.480, all patients with suspected or confirmed TB should be evaluated for possible pregnancy during the diagnostic evaluation**

\_\_\_Yes **Patient was pregnant when TB diagnostic evaluation was performed or initiated**

\_\_\_No **Patient was not pregnant when TB diagnostic evaluation was performed or initiated**

\_\_\_Unknown **It is not known if patient was pregnant when TB diagnostic evaluation was performed or initiated**

\_\_\_Unknown **The biological sex recorded for the patient at birth is not known.**

1. **Ethnicity** **The response to this item should be based on the patients self-identity or self-reporting not on physical appearance or surname**

\_\_\_Hispanic or Latino **Patient considers himself or herself Cuban, Mexican, Puerto Rican, South or Central American, or of other Latin American culture or origin, regardless of race**

\_\_\_Not Hispanic or Latino **Patient does not consider himself/herself Hispanic or Latino**

\_\_\_Unknown **Patient’s ethnicity is not reported or unknown**

1. **Race** **The response to this item should be based on the patient’s self-identity or self-reporting. Patients should be offered the option of selecting one or more racial designation**

\_\_\_American Indian or Alaska Native **Patient has origins in any of the original peoples of North and South America (including Central America)**

\_\_\_Asian (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) **Patient has origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent (e.g., including Bangladesh, Cambodia, China, India, Indonesia, Japan, Korea, Malaysia, Nepal, Pakistan, the Philippine Islands, Thailand, and Vietnam). If patient self-identifies as Asian, please use the detailed race categories below to complete the “Specify” portion:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Asian Indian** | **Filipino** | **Laotian** | **Pakistani** |
| **Bangladeshi** | **Hmong** | **Madagascar** | **Singaporean** |
| **Bhutanese** | **Indonesian** | **Malaysian** | **Sri Lankan** |
| **Burmese** | **Iwo Jiman** | **Maldivian** | **Taiwanese** |
| **Cambodia** | **Japanese** | **Nepalese** | **Thai** |
| **Chinese** | **Korean** | **Okinawan** | **Vietnamese** |

\_\_\_Black or African American **Patient has origins in any of the black racial groups of Africa**

\_\_\_Native Hawaiian or Other Pacific Islander (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) **Patient has origins in any of the original peoples of Hawaii, Guam, American Samoa, or other Pacific Islands, expect islands considered to be part of Asia. If patient self-identifies as Native Hawaiian or Other Pacific Islander (NHOPI), please use the detailed race categories below to complete the “Specify” portion:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Carolinian** | **Kiribati** | **Micronesian** | **Papua New Guinean** | **Solomon Islander** |
| **Chamorro** | **Kosraean** | **Native Hawaiian** | **Pohnpeian** | **Tahitian** |
| **Chuukese** | **Mariana Islander** | **New Hebrides** | **Polynesian** | **Tokelauan** |
| **Fijian** | **Marshallese** | **Other Pacific Islander** | **Saipanese** | **Tongan** |
| **Guamanian** | **Melanesian** | **Palauan** | **Samoan** | **Yapese** |

\_\_\_White **Patient has origins in any of the original peoples of Europe, the Middle East, or North African**

\_\_\_Other Race (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) **Patient identifies to another race not listed above. Please specify what race the patient self-identifies with**

\_\_\_Unknown **Patient’s race is not reported or is unknown**

1. **Nativity \*\*NEW VARIABLE\*\***
	1. Country of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Enter the name of the country in which the person was born. If the person was born in a U.S. territory or a freely associated state, specify the name of the territory or state; do not enter “United States” unless the person was born in one of the 50 U.S. states or the District of Columbia. PROVIDE THE ACTUAL COUNTRY OF BIRTH FOR ALL PATIENTS REGARDLESS OF WHETHER THEY WERE U.S. CITIZENS AT BIRTH**

(If NOT United States, Date of First U.S. Arrival: 🞏🞏/🞏🞏/🞏🞏🞏🞏) **If the person was not born in one of the 50 U.S. states or the District of Columbia, enter the date that the patient first arrived in one of the 50 U.S. states or the District of Columbia. This date should be provided regardless of whether the patient was already a U.S. citizen at the time of first arrival in the United States. If the actual day of the month is unknown, enter “01” For example if the patient arrived in November 2018 but the actual day in November is unknown, enter 11/01/2018**

* 1. Eligible for U.S. Citizenship/Nationality at Birth (regardless of country of birth)?

\_\_\_Yes

**Birth Abroad in Wedlock to Two U.S. Citizen Parents: If the mother and father are U.S. citizens, the child acquires U.S. at birth if one of the parents has had a residence in the U.S. prior to the child’s birth.**

**Birth Abroad in Wedlock to a U.S. Citizen and Alien: The child acquires U.S. citizenship of the U.S. citizen parent has been physically present in the U.S. for ≥5 years.**

**Birth Abroad out of Wedlock:** [**https://travel.state.gov/content/travel/en/legal/travel-legal-considerations/us-citizenship/Acquisition-US-Citizenship-Child-Born-Abroad.htmlhttps://travel.state.gov/content/travel/en/legal/travel-legal-considerations/us-citizenship/Acquisition-US-Citizenship-Child-Born-Abroad.html**](https://travel.state.gov/content/travel/en/legal/travel-legal-considerations/us-citizenship/Acquisition-US-Citizenship-Child-Born-Abroad.html)

\_\_\_No

\_\_\_Unknown

* 1. Countries of Birth for Primary Guardian(s) (pediatric [<15 years old] cases only)
		1. Guardian 1: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
		2. Guardian 2: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
1. **Country of Usual Residence \*\*NEW VARIABLE\*\***
	1. Country of Usual Residence: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Country where the patient usually resides**
	2. If **NOT** U.S. Reporting Area, Has Been in United States for ≥90 days (inclusive of Report Date)?

\_\_\_Yes, **patient remained in the U.S. for ≥90 days inclusive of report date**

\_\_\_No, **patient remained in the U.S. for <90 days inclusive of report date**

\_\_\_Unknown **how long the patient remained in the U.S.**

**Patient was alive at time of lab results confirmed TB diagnosis or the time patient was confirmed as a clinical or provider-verified case or patient was alive when TB medications were started**

1. **Status at TB Diagnosis**

\_\_\_Alive

\_\_\_Dead (Make sure to complete question 43)

**Patient was deceased at the time lab results confirmed TB diagnosis or deceased when patient was confirmed as a clinical or provider-verified case**

1. **Initial Reason Evaluated for TB**

\_\_\_Contact Investigation **Select if TB diagnosis was made based on a contact investigation evaluation and testing results from this investigation**

\_\_\_Screening **Includes any type of planned screening for TB in a specific population (targeted testing, B-notification, employment screening, A&D, shelter)**

\_\_\_TB Symptoms **Select if the patient has TB symptoms at the time of diagnostic evaluation and neither contact investigation or screening apply**

\_\_\_Other **Select if reason for initial evaluation does not fit into any of the above categories**

\_\_\_Unknown **Select if the reason for evaluation is not known**

# Risk Factors

1. **Occupation and Industry \*\*NEW VARIABLE\*\***
	1. Has the patient *ever* worked as one of the following? (select all that apply)

\_\_\_Healthcare Worker **Paid or unpaid person working in a health care setting with potential for exposure to *M. tuberculosis***

\_\_\_Correctional Facility Employee **Person working in a correctional facility**

\_\_\_Migrant/Seasonal Worker **Person who is required to be absent from a permanent place of residences for the purpose of seeking employment**

\_\_\_None of the above **Select if individual never worked as any of the choices above**

\_\_\_Unknown **Select when it cannot be confirmed or denied that the individual every worked as one of the choices above**

* 1. Patient’s Current Occupation(s) and Industry(ies)

|  |  |
| --- | --- |
| OccupationAsk, “What kind of work do you do?” | IndustryAsk, “What kind of business or industry do you work in? |
| Ex.: registered nurse, janitor, roofer | **Ex.: hospital, dairy farm, construction, retail, restaurant** |
|  |  |
|  |  |

1. **Other Risk Factors \*\*NEW VARIABLE\*\***

|  |  |
| --- | --- |
| Risk Factor | Yes/No/Unknown |
| Diabetic at Diagnostic EvaluationCriteria include: * Hemoglobin A1c ≥6.5%, or
* Fasting plasma glucose ≥126 mg/dL, or
* 2-hour plasma glucose ≥200 mg/dL during an oral glucose tolerance test, or
* In a patient with classic symptoms of hyperglycemia or hyperglycemia crisis, a random plasma glucose ≥200 mg/dL
 |  |
| Homeless in the Past 12 MonthsDefinition for homeless:* No fixed, regular, and adequate nighttime residence, and
* A primary nighttime residence that is
	+ A supervised publicly or privately operated shelter designated to provide temporary living accommodations, or
	+ An institution that provides a temporary residence for individuals intended to be institutionalized, or
	+ A public or private place not designated for, or ordinarily used as, a regular sleeping accommodation for human beings
* May also be defined as a person who has no home or has unstable housing situations
* May also be defined as a person who lacks customary and regular access to a conventional dwelling or residence
 |  |
| Homeless Ever (See above) |  |
| Resident of Correctional Facility at Diagnostic EvaluationPatient was incarcerated or detained in a jail, prison, or other detention center when TB diagnostic evaluation was performed or initiated |  |
| Resident of Correctional Facility Ever (See above)Patient was a resident of a long-term care facility when TB diagnostic evaluation was performed or initiated  |  |
| Resident of Long-Term Care Facility at Diagnostic Evaluation(See above) |  |
| Injecting Drug Use in the Past 12 MonthsPatient used injecting drugs in the past 12 months not prescribed by a healthcare provider. Injecting drug use involves the use of hypodermic needles and syringes for the injection of drugs not prescribed by a healthcare provider. Route of administration may be intravenous, subcutaneous (e.g., skin popping), or intramuscular. Commonly injected drugs include: heroin and other opiates, cocaine, methamphetamines, amphetamines, PCP, other hallucinogens, barbiturates, steroids, other hormones, other stimulants |  |
| Noninjecting Drug Use in the Past 12 MonthsPatient used non-injection drugs in the past 12 months not prescribed by a healthcare provider or approved by FDA for over-the-counter dispensing. Involves the use of licensed or prescription drugs or other drugs that were not injected and were not prescribed by a healthcare provider or approved for over-the-counter use by FDA, or misuse of prescribed drugs. Drugs may be ingested, inhaled, sniffed, or smoked. Marijuana use should always be recorded as non-injecting drug use, regardless of whether marijuana is legal for medicinal or recreational use in the state of residence. |  |
| Heavy Alcohol Use in the Past 12 MonthsPatient heavily used alcohol in the past 12 months. Heavy alcohol use is defined as binge drinking on ≥5 days in the month preceding diagnosis. Binge drinking is defined as a pattern of drinking that bring blood alcohol concentration levels to 0.08 g/dL. This typically occurs after 4 drinks for women and 5 drinks for men in about 2 hours. |  |
| TNF-α Antagonist TherapyPatient recently received, or was receiving, tumor necrosis factor-alpha (TNF-α) antagonist therapy when TB diagnostic evaluation was performed or initiated. |  |
| Post-Organ TransplantationPatient has ever received a solid organ transplant (e.g., kidney, heart, lung) |  |
| End Stage Renal DiseasePatient had end-stage regnal disease when TB diagnostic evaluation was performed or initiated (e.g., patient on dialysis) |  |
| Viral Hepatitis (B or C only)Patient has ever had a diagnosis of Hepatitis B or C (acute or chronic) |  |
| Other Immunocompromise (other than HIV/AIDS)Patient is immunocompromised because of either a medical condition (e.g., leukemia, Hodgkin’s lymphoma, carcinoma of the head or neck), or immunosuppressive therapy, such as prolonged use of high-doses of corticosteroids |  |
| Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)Additional risk factors may be entered as “Other” and specified in the “specify” field |  |

1. **If Resident of Correctional Facility at Diagnostic Evaluation, Type of Facility?**

\_\_\_Federal Prison **Confinement facility administered by a federal agency (except ICE); includes privately operated federal correctional facilities**

\_\_\_State Prison **Confinement facility administered by a state agency, includes privately operated state correctional facilities**

\_\_\_Local Jail **Confinement facility usually administered by a local law enforcement agency, intended for adults but sometimes also containing juveniles; holds persons detained pending adjudication and/or persons committed after adjudication typically for sentences of ≤1 year**

\_\_\_Juvenile Correction Facility **Public or private residential facility; includes juvenile detention centers, reception and diagnostic centers, ranches, farms, boot camps, residential treatment centers, and halfway houses or group homes designated specifically for juveniles**

\_\_\_Other Correctional Facility **Includes ICE detention centers, Indian reservation facilities, military stockades and jails, federal park police facilities, police lockups (temporary holding facilities for persons who have not been formally charged in court), or other correctional facilities not listed above**

\_\_\_Unknown **Inmate when the TB diagnostic evaluation was performed, but the type of correctional facility is not known**

1. **If Resident of Long-Term Care Facility at Diagnostic Evaluation, Type of Facility?**

\_\_\_Nursing Home **Freestanding facility with ≥3 beds that provides nursing care services**

\_\_\_Hospital-Based Facility **Distinct unit with ≥3 beds that is physically attached to, or managed by, a hospital**

\_\_\_Residential Facility **Facility with ≥3 beds and that meets both of the following criteria (1) Not classified as a nursing home, hospital-based facility, mental health residential facility, or alcohol or drug treatment facility; and (2) Provides personal care or supervision to its residents, in additional to room and board (e.g., help with bathing, dressing, eating, walking, shopping)**

\_\_\_Mental Health Residential Facility **Facility that provides 24-hour care in a hospital, residential treatment, or supportive setting. Includes state, local and private psychiatric hospitals, VA facilities, residential mental health treatment centers for children, and multiservice mental health residential treatment programs**

\_\_\_Alcohol or Drug Treatment Facility **Only long-term rehabilitation or residential facilities designated for treatment of ≥30 days. Excludes ambulatory or outpatient facilities, detoxification units, and facilities designated for <30 days of treatment.**

\_\_\_Other Long-Term Care Facility **A facility not mentioned above that is designated for treatment of ≥30 days and facility type is unknown**

\_\_\_Unknown **Patient is known to be a resident of a long-term care facility, but the type of facility is not known**

1. **Current Smoking Status at Diagnostic Evaluation** **\*\*NEW VARIABLE\*\***

**The definition of smoking includes consumption of tobacco (or nicotine) through combustible tobacco products (e.g., cigarettes) or electronic nicotine delivery systems (ENDS; e.g., vapes or e-cigarettes). It does not include chewing tobacco. Smoking substances other than nicotine (e.g., marijuana) should be recorded under non-injecting drug use**

\_\_\_Current everyday smoker **Patient currently smokes every day**

\_\_\_Current someday smoker **Patient smokes some days but not every day**

\_\_\_Former smoker **Patient has smoked at least 100 cigarettes/cigars in his/her lifetime and has quit**

\_\_\_Never smoker **Patient has not smoked at least 100 cigarettes/cigars n his/her lifetime**

\_\_\_Smoker, current status unknown **Patient was a smoker, but current status is unknown**

\_\_\_Unknown if ever smoked **Patient’s tobacco smoking history is not known**

1. **Lived outside of the United States for >2 months (uninterrupted)?**

\_\_\_Yes **Patient indicates that he/she has resided or traveled outside of the U.S. for >2 months (uninterrupted)**

\_\_\_No **Patient did not live or travel outside of the U.S. >2 months (uninterrupted)**

\_\_\_Unknown **No information is known about patient’s travel history**

# Diagnostic Testing (Non-DST)

1. **Tuberculin Skin Test and All Non-DST TB Laboratory Test Results (required results prefilled in table; unlimited number of additional results may be entered)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| TestType | SpecimenSource Site | Date Collected/Placed | Date Reported/Read | Test Result (Qual.)Positive/ Negative/ Indeterminate/ Not Done/ Unk | Test Result (Quant.)Tests with a quantitative (numerical) results | Test Result(Units of Measure) |
| TSTTuberculin Skin Test—If a person has a previously documented negative test and now the test is positive, record both the previous negative and current positive result.  | Skin Structure | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | **Positive/ Negative/ Indeterminate/ Not Done/ Unk****Initial TST should be entered or marked “Not Done” is test not done** | **Record quantitative result** | mm of induration |
| IGRA [spec. type]Interferon Gamma Release Assay—specify if the test is a QuantiFERON Gold-Plus (QFT) or T-spot test. If a person has a previously documented negative test and now the test is positive, record both the previous negative and current positive result | Blood | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | **Positive/ Negative/ Indeterminate/ Not Done/ Unk****Initial IGRA should be entered or marked “Not Done” is test not done** | **Not required for IGRA tests** | N/A |
| SmearMicroscopic examination of specimen e.g., sputum, using smear technique | Sputum**For sputum specimens, select “sputum” from the value set, not “trachea,” “lung structure,” etc.** | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | **Positive/ Negative/ Indeterminate/ Not Done/ Unk****Initial sputum smear should be entered or marked “Not Done” is test not done** | **Example: <1, 1-10, 10+, 1+, 2+, etc.** | N/A |
| Pathology/CytologyMicroscopic examination of specimen using histopathological or cytological methods |  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | **Positive/ Negative/ Indeterminate/ Not Done/ Unk** |  |  |
| CultureMycobacterial culture of specimen to determine presence of *M. tuberculosis* complex (not nontuberculous mycobacteria) | Sputum**For sputum specimens, select “sputum” from the value set, not “trachea,” “lung structure,” etc.** | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | **Positive/ Negative/ Indeterminate/ Not Done/ Unk****Initial sputum culture should be entered or marked “Not Done” is test not done** | N/A | N/A |
| NAANucleic acid amplification testing (only when the specimen is tested directly; do not include results from tests on isolates obtained via culture) | Sputum**For sputum specimens, select “sputum” from the value set, not “trachea,” “lung structure,” etc.** | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | **Positive/ Negative/ Indeterminate/ Not Done/ Unk****Initial NAAT should be entered or marked “Not Done” is test not done** | N/A | N/A |
| HIVSerologic test for human immunodeficiency virus infection. Patient self-report of HIV-status is not acceptable. HIV serology results must be documented.  | Blood | 🞏🞏/🞏🞏/🞏🞏🞏🞏**A positive documented test can be from any date; a negative test must be documented ≤12 months before the TB diagnostic evaluation** | 🞏🞏/🞏🞏/🞏🞏🞏🞏**A positive documented test can be from any date; a negative test must be documented ≤12 months before the TB diagnostic evaluation** | **Positive/ Negative/ Indeterminate/ Not Done/ Unk** | N/A | N/A |
| CD4 CountResult of test for CD4 T-lymphocytes. Typically done with HIV patients to characterize the patient’s immune status. At least one (1) CD4 count should be reported for HIV-positive patients, as close to the time of TB diagnostic evaluation as possible. Subsequent CD4 counts may also be reported. |  |  |  | N/A | **Record quantitative result** | **Cell count** |
| Hemoglobin A1cResult of test to determine the average glucose level for the preceding several months. Typically done with diabetic patients or persons being screened for diabetes. At least one (1) hemoglobin A1c or fasting blood glucose should be reported for diabetic patients, as close to the time of TB diagnostic evaluation as possible. Subsequent hemoglobin A1c results may also be reported. |  |  |  | N/A | **Record quantitative result** | **Percentage** |
| Fasting Blood GlucoseResult of test to determine the blood glucose at any given moment in a patient who has not eaten in several hours. Typically done with patients or persons being screened for diabetes. At least one hemoglobin A1c or fasting blood glucose should be reported for diabetic patients, as close to the time of TB diagnostic evaluation as possible. Subsequent fasting blood glucose results may also be reported. |  |  |  | N/A | **Record quantitative result** | **Milligrams per deciliter** |
| OtherAny other diagnostic tests that the reporting area wishes to include |  |  |  |  |  |  |

**Test Type Options:** Smear, Pathology, Cytology, NAA, Culture, TST, IGRA-QFT, IGRA-TSpot, IGRA-Unknown, HIV, CD4 Count, Hemoglobin A1c, Fasting Blood Glucose, Other (specify), etc.

**Test Result (Qualitative) Options:** Positive, Negative, Borderline, Indeterminate, Not Done, Unknown

**Test Result (Units of Measure) Options:** Millimeters of Induration (TST), Cell Count (CD4), Percentage (HGB-A1c), Milligrams per deciliter (FBG), Other Units as Appropriate

1. **Chest Radiograph or Other Chest Imaging Study Results (required results prefilled in table; unlimited number of additional results may be entered)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Type | Date of Study | Result | Cavity? | Miliary? |
| Plain Chest X-RayStandard radiological study resulting in a 2-dimensional projection of internal thoracic structures onto film or a screen | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | **Consistent with TB: Any initial result showing abnormalities (e.g., hilar adenopathy, effusion, infiltrate[s], cavity, scarring) consistent with TB****Not Consistent with TB: Results showed no abnormalities consistent with TB. This category includes other abnormalities that are not consistent with TB****Not Done: Used to indicate the test was not done.****Unknown: Result of chest imaging is not known** | **Yes: The chest imaging study showed evidence of one or more cavities****No: Results did not show evidence of one or more cavities****Unknown: It is not known if results showed evidence of one or more cavities** | **Yes: Results showed evident of miliary disease (e.g., miliary TB, or miliary or bilateral micronodular pattern)****No: Results did not show evidence of miliary disease (e.g., miliary TB, or miliary or bilateral micronodular pattern).****Unknown: It is not known if results showed evidence of miliary disease (e.g., miliary TB, or miliary or bilateral micronodulary pattern)** |
| CT ScanComputed tomography, an advanced imaging technique using X-rays to display 3-dimensional images or thoracic structures with computer assistance | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | **Consistent with TB: Any initial result showing abnormalities (e.g., hilar adenopathy, effusion, infiltrate[s], cavity, scarring) consistent with TB****Not Consistent with TB: Results showed no abnormalities consistent with TB. This category includes other abnormalities that are not consistent with TB****Not Done: Used to indicate the test was not done.****Unknown: Result of chest imaging is not known** | **Yes: The chest imaging study showed evidence of one or more cavities****No: Results did not show evidence of one or more cavities****Unknown: It is not known if results showed evidence of one or more cavities** | **Yes: Results showed evident of miliary disease (e.g., miliary TB, or miliary or bilateral micronodular pattern)****No: Results did not show evidence of miliary disease (e.g., miliary TB, or miliary or bilateral micronodular pattern).****Unknown: It is not known if results showed evidence of miliary disease (e.g., miliary TB, or miliary or bilateral micronodulary pattern)** |
| MRIMagnetic resonance imaging, an advanced imaging technic using strong magnetic fields to display 3-dimensional images of thoracic structures with computer assistance |  | **Consistent with TB: Any initial result showing abnormalities (e.g., hilar adenopathy, effusion, infiltrate[s], cavity, scarring) consistent with TB****Not Consistent with TB: Results showed no abnormalities consistent with TB. This category includes other abnormalities that are not consistent with TB****Not Done: Used to indicate the test was not done.****Unknown: Result of chest imaging is not known** | **Yes: The chest imaging study showed evidence of one or more cavities****No: Results did not show evidence of one or more cavities****Unknown: It is not known if results showed evidence of one or more cavities** | **Yes: Results showed evident of miliary disease (e.g., miliary TB, or miliary or bilateral micronodular pattern)****No: Results did not show evidence of miliary disease (e.g., miliary TB, or miliary or bilateral micronodular pattern).****Unknown: It is not known if results showed evidence of miliary disease (e.g., miliary TB, or miliary or bilateral micronodulary pattern)** |
| PETPositron emission tomography, an advanced imaging technique that uses radioactive tracers to identify areas of higher chemical activitiy in the body |  | **Consistent with TB: Any initial result showing abnormalities (e.g., hilar adenopathy, effusion, infiltrate[s], cavity, scarring) consistent with TB****Not Consistent with TB: Results showed no abnormalities consistent with TB. This category includes other abnormalities that are not consistent with TB****Not Done: Used to indicate the test was not done.****Unknown: Result of chest imaging is not known** | **Yes: The chest imaging study showed evidence of one or more cavities****No: Results did not show evidence of one or more cavities****Unknown: It is not known if results showed evidence of one or more cavities** | **Yes: Results showed evident of miliary disease (e.g., miliary TB, or miliary or bilateral micronodular pattern)****No: Results did not show evidence of miliary disease (e.g., miliary TB, or miliary or bilateral micronodular pattern).****Unknown: It is not known if results showed evidence of miliary disease (e.g., miliary TB, or miliary or bilateral micronodulary pattern)** |

**Study Type Options:** Plain Radiograph, CT Scan, MRI, PET, Other

**Result Options:** Not Consistent with TB **results showed no abnormalities consistent with TB; includes other abnormalities not consistent with TB**,

Consistent with TB **any initial results showing abnormalities (e.g., hilar adenopathy, effusion, infiltrates, cavity, scaring) consistent with TB**

Not Done **Used to indicate that a chest X-ray or chest CT was not done in this case**

Unknown **Result of the chest imaging is not known**

**Cavity Options**: Yes **(chest imaging study showed evidence of ≥1 cavities)**,

No **(results did not show evidence of ≥1 cavities)**,

Unknown **(it is not known if results showed evidence of ≥1 cavitites)**

**Miliary Options**: Yes **(results showed evidence or miliary disease—miliary TB or miliary or bilateral micronodular pattern)**,

No **(results did not miliary disease—miliary TB or miliary or bilateral nodular pattern**,

Unknown **It is not known if results showed evidence of miliary disese—miliary TB, or miliary or bilateral micronodular pattern**

**Miliary is a clinical or radiologic finding, rather than a site of disease. Miliary TB is the result of a TB infection eroding into the bloodstream and from there disseminating**

**throughout the body to multiple organs. It appears on radiographs as a great number of small (1- to 2-mm), well-defined nodules that look like millet seeds scattered throughout the lungs.**

# Clinical History and Findings

1. **Has the Patient been Previously Diagnosed with TB Disease or LTBI?**

\_\_\_Yes **The patient has a history of previous TB disease or TBI diagnoses. Written documentation of the previous episode is ideal; however, self-report is acceptable**

\_\_\_No **The patient did not have previous TB disease or TBI diagnoses**

\_\_\_Unknown **It is not known if the patient had previous TBI disease or TBI diagnoses**

**If YES, Complete Table Below (unlimited number of rows may be entered):**

|  |  |  |  |
| --- | --- | --- | --- |
| Diagnosis Type(TB Disease/LTBI) | Date of DiagnosisDate of previous diagnosis (provide date to the level of specificity that is available; self-report is acceptable) | Previous State Case No.Central Office will complete this field | Completed Treatment?(Yes/No/Unknown)Written documentation of the previous TB disease or TBI is preferred. If the patient had a previous episode that was reported to U.S. surveillance, contact central office to obtain information about previous diagnoses and outcomes; otherwise, self-report is accpetable |
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|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |

1. **Date of Illness Onset/Symptom Start Date:** 🞏🞏/🞏🞏/🞏🞏🞏🞏 **\*\*NEW VARIABLE\*\***

**Date illness/symptoms started for this TB episode. Some symptoms of TB can be non-specific. The symptom onset date should be recorded as the approximate time when the patient first noticed one or more of the following symptoms:**

* **Severe cough that lasted ≥3 weeks**
* **Chest pain not explained by another condition**
* **Coughing up blood or sputum**
* **Night sweats**
* **Persistent fever not explained by another condition**
* **Unintentional weight loss not explained by another condition**
* **Poor weight gain (children)**
* **Growth delay (children)**
* **Lethargy (children)**
* **Irritability (children—symptom of TB meningitis)**
* **Neck stiffness (TB meningitis)**
* **Vomiting (TB meningitis) not explained by another condition**
* **Headache (TB meningitis) not explained by another condition**
1. **Site of TB Disease** (**select all that apply**)

\_\_\_Pulmonary

\_\_\_Pleural

\_\_\_Lymphatic: Cervical

\_\_\_Lymphatic: Intrathoracic

\_\_\_Lymphatic: Axillary

\_\_\_Lymphatic: Other

\_\_\_Lymphatic: Unknown

\_\_\_Laryngeal

\_\_\_Bone and/or Joint

\_\_\_Genitourinary

\_\_\_Meningeal

\_\_\_Peritoneal

\_\_\_Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

\_\_\_Site Not Stated

# Epidemiologic Investigation

1. **Case Meets Binational Reporting Criteria? \*\*NEW VARIABLE\*\***

\_\_\_Yes

If Yes, Which Criteria were Met? (**Select All That Apply**)

\_\_\_Exposure to Suspected Product from Canada or Mexico (e.g., dairy product for *M. bovis* case)

\_\_\_Has Case Contacts In or From Mexico or Canada **Patient has close contacts who live in Mexico or Canada**

\_\_\_Potentially Exposed by a Resident of Mexico or Canada **Patient was potentially exposed to a TB patient from Mexico or Canada**

\_\_\_Potentially Exposed while in Mexico or Canada **Patient was potentially exposed while physically in Mexico or Canada**

\_\_\_Resident of Canada or Mexico **The patient is a resident of Mexico or Canada**

\_\_\_Other Situations that May Require Binational Notification or Coordination of Response **Select this option if the case meets one of the following descriptions: (1) Patient crossed the border into the U.S. from Mexico during TB treatment, or (2) Patient was referred to the U.S.-funded, binational TB program for treatment continuity (i.e., a patient who was being treated in the U.S. but it was known that he or she would cross the border to Mexico.**

\_\_\_No **The case does not meet binational reporting criteria**

\_\_\_Unknown

1. **Case Identified During the Contact Investigation of Another Case?** **\*\*NEW VARIABLE\*\***

\_\_\_Yes **Case was identified during the contact investigation of another case**

If Yes, Evaluated for TB During that Contact Investigation?

\_\_\_Yes **Patient was evaluated for TB during the contact investigation, regardless of whether the patient was diagnosed with TB as part of that evaluation**

\_\_\_No **Patient was not evaluated for TB during that contact investigation**

\_\_\_Unknown **It is not known if the patient was evaluated for TB during that contact investigation**

\_\_\_No **Case was not identified during the contact investigation of another case**

\_\_\_Unknown **It is not known if the case was identified during the contact investigation of another case**

1. **Contact Investigation Conducted for This Case? \*\*NEW VARIABLE\*\***

\_\_\_Yes **Contact investigation was conducted for this case**

\_\_\_No **Contact investigation was not conducted for this case**

\_\_\_Unknown **It is not known if contact investigation was conducted for this case**

1. **Complete Table Below for All Known TB and LTBI Cases Epidemiologically Linked to this Case
(an unlimited number of rows may be entered): \*\*NEW VARIABLE\*\***

**If additional confirmed cases of TB are linked to this case, central office will add the additional case numbers.**

**Patients diagnosed with TBI that are linked to this case are not assigned a case number.**

|  |
| --- |
| State Case Number |
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| 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |
| 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |

# Initial Treatment Information

1. **Date Therapy Started:** 🞏🞏/🞏🞏/🞏🞏🞏🞏

**Date the patient began a multidrug regimen for confirmed or possible TB disease. The following is the hierarchy of determining the date therapy started:**

1. **Date patient first ingested medication if documented in a medical record such as a hospital, clinic, or directly observed therapy (DOT) record (THIS IS THE PREFERRED DATE TO USE FOR DATE THERAPY STARTED)**
2. **Date medication was first dispensed to the patient as documented by medical or pharmacy record (THIS IS THE 2nd PREFERRED ALTERNATIVE besides #1)**
3. **Date medication was first prescribed to the patient by the healthcare provider as documented by medical or pharmacy record (THIS IS THE LAST ALTERNATIVE FOR DATE THERAPY STARTED IF #1 and #2 CANNOT BE USED)**
4. **Initial Drug Regimen**

|  |  |
| --- | --- |
| Drug Name  | Used? (Yes/No/Unknown) |
| Isoniazid |  |
| Rifampin |  |
| Pyrazinamide |  |
| Ethambutol |  |
| Streptomycin |  |
| Rifabutin |  |
| Rifapentine |  |
| Ethionamide |  |
| Amikacin |  |
| Kanamycin |  |
| Capreomycin |  |
| Ciprofloxacin |  |
| Levofloxacin |  |
| Ofloxacin |  |
| Moxifloxacin |  |
| Cycloserine |  |
| Para-Amino Salicylic Acid |  |
| Linezolid |  |
| Bedaquiline |  |
| Delamanid |  |
| Clofazimine |  |
| Pretomanid |  |
| Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

**Select “YES” if the drug is known to be part of the initial regimen. “YES” indicates that the drug was initially prescribed for treatment of TB disease.**

**Select “NO” if the drug is known to not be part of the initial regimen.**

**Select “UNKNOWN” if it is not known if the drug is part of the initial regimen.**

**For combination drug, select “YES” for each drug that is a component of the combination drug.**

**Example: Rifamate—select “YES” for Isoniazid and Rifampin**

**Example: Rifater—select “YES” for Isoniazid, Rifampin, and Pyrazinamide**

1. **If Initial Drug Regimen NOT RIPE/HRZE, Why Not? \*\*NEW VARIABLE\*\***

**ANSWER THIS QUESTION ONLY IF RIPE/HRZE WAS NOT USED**

\_\_\_Drug contraindication/interaction **There was a pharmacological contraindication or interaction that prevented the use of RIPE/HRZE in this patient**

\_\_\_Drug susceptibility testing results already known **The patient’s drug susceptibility results were already known, so a treatment regimen based on susceptibility results was used immediately**
\_\_\_Suspected drug resistance **Drug susceptibility testing results were not yet available, but the provider suspected drug resistance (e.g., the patient was a contact to a drug-resistant TB case), so a different regimen was used**
\_\_\_Drug shortage **One or more of the RIPE/HRZE drugs could not be used because of national or local shortage of the drug(s).**

\_\_\_Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) **Other reason not covered in one of the above categories**

\_\_\_Unknown **There is insufficient documentation to determine why a regimen other than standard first-line therapy was used**

# Genotyping and Drug Susceptibility Testing

1. **Isolate Submitted for Genotyping? Central Office will complete this question**

\_\_\_Yes (Accession Number:🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏)

\_\_\_No

1. **Was Phenotypic/Growth-Based Drug Susceptibility Testing Done? Phenotypic/growth-based drug susceptibility testing is the conventional drug susceptibility testing performed by the Tennessee Department of Health, Division of Laboratory Services**

\_\_\_Yes **Growth-based drug susceptibility testing was performed**

\_\_\_No **Growth-based drug susceptibility testing was not performed**

\_\_\_Unknown **It is unknown whether growth-based susceptibility testing was performed**

**If YES, Complete Table Below (an unlimited number of rows may be entered): An answer should be provided for every drug listed**

**INCLUDE INITIAL RESULT FOR ALL DRUGS LISTED AS WELL AS ANY SUBSEQUENT TESTS WHERE RESULT CHANGED**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Drug Name | Date CollectedMonth, day, and year the specimen was collected | Date ReportedMonth, day, and year the laboratory reported the result. This date can be found on the lab report as the date the report is released or made available. If the result date and report date are not the same, use the earliest date available | Specimen Source | Result(Sus./Res./Unk./Not Done)Susceptible: Select only if completely susceptibleResistant: ANY degree of resistance reported for the drugUnknown: It is not known whether the test was performed or results were not available or result is not known for reason other than pending resultsNot Done: Susceptibility testing was not performed for that specific drug |
| Isoniazid | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Rifampin | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Pyrazinamide | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Ethambutol | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Streptomycin | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Rifabutin | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Rifapentine | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Ethionamide | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Amikacin | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Kanamycin | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Capreomycin | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Ciprofloxacin | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Levofloxacin | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Ofloxacin | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Moxifloxacin | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Other Quinolones | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Cycloserine | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Para-Amino Salicylic Acid | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Bedaquiline | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Clofazimine | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Delamanid | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Linezolid | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| Pretomanid | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Resistant: any degree of resistance is reported**

**Susceptible: Select only if complete susceptible**

**Unknown: It is not known whether the test was performed, or results were not available or result is not known for a reason other than pending results**

1. **Was Genotypic/Molecular Drug Susceptibility Testing Done?** **\*\*NEW VARIABLE\*\***

**Central Office will complete this question**

\_\_\_Yes

\_\_\_No

\_\_\_Unknown

**If YES, Complete Table Below (an unlimited number of rows may be entered): Central Office will complete the table, if applicable**

**INCLUDE INITIAL RESULT FOR EACH COMBINATION OF GENE AND TEST TYPE AS WELL AS ANY SUBSEQUENT TESTS WHERE THE RESULT CHANGED**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Gene Name | Date Coll. | Date Rep. | Spec. Srce | Result | NA Change | AA Change | INDEL | Test Type |
|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |
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|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |
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|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |
|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |
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**Results Options:** Mutation Detected, Mutation Not Detected, Unknown

**Indel Options:** Insertion, Deletion, Indel (not otherwise specified), Unknown

**Test Type Options:** Nonsequencing, Sequencing, Other, Unknown

1. **Was the Patient Treated as an MDR TB Case (Regardless of DST Results)? \*\*NEW VARIABLE\*\***

**This will include patients that are confirmed by susceptibility results, those treated as a clinical case or provider-verified case that is a known contact to an MDR TB case and started on an MDR TB regimen, and patients who are started on an MDR TB regimen (who are pansensitive) due to reasons such as medication intolerance (of INH or RIF) or contraindication of medications.**

\_\_\_Yes **The patient was treated as an MDR TB case. Definition of MDR TB is resistance to both Isoniazid (INH) and Rifampin (RIF)**

\_\_\_No **The patient was not treated as an MDR TB case.**

\_\_\_Unknown **It is not known whether the patient was treated as an MDR TB case**

**If YES, complete MDR TB Supplemental Data Form**

# Case Outcome

1. **Sputum Culture Conversion Documented? 2025 NTIP Target: 83%**

\_\_\_Yes (Date specimen collected for FIRST consistently negative sputum culture: 🞏🞏/🞏🞏/🞏🞏🞏🞏)

**Initial sputum specimen was culture-positive, followed by at least one (1) negative sputum culture (not within the initial set of sputa). There should be NO positive cultures**

**after the negative culture(s) and no other positive cultures within the same “set” of sputa**

\_\_\_No **Initial sputum specimen was culture-positive, and no subsequent sputum specimens were culture-negative. Example: all follow-up cultures were positive, patient could not produce sputum after therapy started, or no follow-up sputum cultures were obtained**

If No, Reason for Not Documenting Sputum Culture Conversion?

\_\_\_No Follow-up Sputum Despite Induction **Repeat sputum collection was attempted (including induced sputum collection), but because of clinical improvement, patient was not able to produce sputum**

\_\_\_No Follow-up Sputum and No Induction **Repeat sputum collection was attempted, but induced sputum collection was not attempted and patient was not able to produce sputum**
\_\_\_Died **Patient died before having an opportunity to submit sputum to document whether the sputum culture had converted**
\_\_\_Patient Refused **Patient refused to provide a sputum specimen for repeat culture**

\_\_\_Patient Lost to Follow-up **Patient was lost to follow-up before having an opportunity to submit a sputum to document whether the sputum culture had converted**

\_\_\_Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) **A reason not included in the above choices (e.g., treatment failed, or the patient moved outside of the U.S.)**

\_\_\_Unknown **It is not known why a repeat sputum culture was not obtained**

\_\_\_Unknown **Results of all follow-up cultures are not known, or it is not known whether follow-up cultures were done**

1. **Moved During Therapy?**

\_\_\_Yes **Patient moved to an area where another reporting area must now provide or coordinate TB care**

If Yes, Moved to Where? (select all that apply)

\_\_\_Out of State (Specify Destination: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) **Patient moved from one U.S. reporting area to another reporting area. U.S. reporting areas include: the 50 U.S. states, District of Columbia, New York City (separate from NY state), Puerto Rico, U.S. Virgin Islands, Guam, American Samoa, Commonwealth of the Northern Marianas Islands, Republic of the Marshall Islands, Federated States of Micronesia, Republic of Palau**

\_\_\_Out of United States (Specify Destination: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) **Patient moved from a U.S. reporting area to a country not considered a U.S. reporting area**

Transnational Referral Made?

\_\_\_Yes **Patient was referred to a TB program or physician outside the U.S. such as through TBNet or CureTB**

\_\_\_No **Patient was not referred to a TB program or physician outside the U.S.**

\_\_\_Unknown

\_\_\_No **Patient did not move out of state or moved within the state**

\_\_\_Unknown

1. **Date Therapy Stopped:** 🞏🞏/🞏🞏/🞏🞏🞏🞏 **2025 NTIP Objective: 95%**

**Date the patient stopped taking medication for confirmed or TB disease. Patient self-report without medical documentation is not acceptable. The following is the hierarchy that should be used for this question:**

1. **Date patient last ingested medication (PREFERRED OPTION)**
2. **Date medication dispensed to the patient would have run out if the patient had taken all of the medication (2nd ALTERNATIVE)**
3. **Date medication prescribed to the patient would have run out of the patient had taken all of the medication from the date of prescription (LAST ALTERNATIVE IF OPTIONS #1 AND #2 CANNOT BE USED)**
4. **Reason Therapy Stopped or Never Started?**

\_\_\_Completed Treatment **Patient completed the prescribed course of therapy per the medical record as recorded by the clinician caring for the patient**

\_\_\_Lost **Patient could not be located before the start or completion of treatment (e.g., the patient moved to an unknown location, or the forwarding address is known but the patient was not found at that address)**

\_\_\_Patient Choice (Uncooperative or Refused) **Patient refused to start or complete therapy (e.g., stopped taking drugs)**

\_\_\_Adverse Treatment Event **Therapy was permanently stopped because of an adverse event due to anti-TB medication. Select this option ONLY if the patient survived the adverse event.**

\_\_\_Not TB **Completed diagnostic evaluation did not substantiate the diagnosis of TB (e.g., *M. avium* or *M. bovis* BCG was isolated from a clinical specimen)**

\_\_\_Died **Patient was alive at diagnosis but died before the state or completion of treatment. Select if the patient died because of adverse treatment event.**

\_\_\_Dying (treatment stopped because of imminent death, regardless of cause of death) **Treatment was stopped by the clinician or at the patient request (or family request) because the patient’s condition was terminal and death was imminent.**

\_\_\_Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) **Therapy was discontinued for a known reason not included in the above choices and is not Unknown (e.g., patient moved outside the U.S., or patient moved to another state and the other state did not follow up)**

\_\_\_Unknown **Reason that therapy was stopped is not known**

1. **Reason TB Disease Therapy Extended >12 Months, if applicable** (select all that apply)

\_\_\_Inability to Use Rifampin (Resistance, Intolerance, etc.) **Rifampin (or another rifamycin) could not be used to treat the patient (e.g., drug-resistant TB, rifampin intolerance), resulting in the treatment protocol lasting more than 12 months**

\_\_\_Adverse Drug Reaction **Patient had a significant adverse drug reaction or experience an adverse treatment event from anti-TB medications that prolonged therapy**

\_\_\_Nonadherence **There were barriers to the patient’s adherence to anti-TB therapy (e.g., treatment interruption), resulting**

\_\_\_Failure **A culture tested positive ≥4 months after treatment began, resulting in prolonged therapy**

\_\_\_Clinically Indicated for Reasons Other than Above **Clinical indications (other than adverse drug reaction) include central nervous system TB (e.g., meningitis), severe liver disease, or other criteria as specified by the clinician**

\_\_\_Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) **Reason does not include any of the choices listed above. Specify the reason that therapy was extended**

\_\_\_Unknown **Reason is unknown**

1. **Treatment Administration** (select all that apply)

\_\_\_DOT (Directly Observed Therapy, in person) **Directly Observed Therapy (DOT), in person. Response applies if DOT was used for any doses for a patient. DOT, or supervised therapy, involves the direct visual observation by a health care provider or other reliable trained person of a patient’s ingestion of medication. Delivering medication to a patient without visual confirmation of ingestion does not constitute DOT.**

\_\_\_EDOT (Electronic DOT, via video call or other electronic method) **Electronic DOT, via video call or other electronic method (synchronous or asynchronous). Response applies if eDOT was used to document adherence to the medication regimen for any doses.**

\_\_\_Self-Administered **Any doses of medication were taken by the patient not under DOT or eDOT (including weekend doses)**

1. **Did the Patient Die (either before diagnosis or at any time while being followed by TB program)?** **\*\*NEW VARIABLE\*\***

\_\_\_\_Yes (Date of Death: 🞏🞏/🞏🞏/🞏🞏🞏🞏) **The patient died (for any reason) either before the TB diagnosis was made**

**or at any point after TB diagnosis while the TB program was following the status of the patient. If this option is selected, record the date of death.**

Did TB or Complications of TB Treatment Contribute to Death?

\_\_\_Yes **TB or complications of TB treatment contributed to death. Written documentation of the cause of death (e.g., death certificate, autopsy report, medical record) is recommended. However, oral information from a reliable source such as a healthcare provider will be accepted. A death certificate is not necessarily required to complete this field, and TB does not need to be listed as a cause of death on the death certificate to conclude that the death was TB-related for the purposes of the RVCT**

\_\_\_No **TB or complications of TB treatment did not contribute to death. TB was not the immediate case, an underlying cause, or another significant condition contributing to death**
\_\_\_Unknown **It is not known if TB or complications of TB treatment contributed to death. Every effort should be made to determine if the death was related to TB disease before classifying as unknown**

\_\_\_\_No **The patient was alive at the time that the TB program stopped following up with the patient**

\_\_\_\_Unknown **It is unknown whether the patient was alive or dead at the time the TB program stopped following up with the patient**

**END OF RVCT**

|  |
| --- |
| MDR TB SUPPLEMENTAL SURVEILLANCE FORMTo be completed for all cases treated as MDR TB, regardless of DST results |
| 1. **History of treatment before current episode with second-line TB drugs for the treatment of TB disease (not LTBI)?**
 | [ ]  Yes [ ]  No [ ]  Unknown **Yes—patient has a history of treatment with second-line medication (e.g., medication used to treat TB that is resistant to first-line drugs). When documentation is not available, self-report of treatment for previous episode of MDR-TB disease is acceptable.****No—patient has not been treated in the past with second-line TB medications.****Unknown—it is not known whether the patient was treated with second-line TB medications** |
| **TREATMENT COURSE** |
| 1. **Date MDR TB therapy started for current episode**

**Date the patient first began a drug regimen containing at least two (2) second-line drugs** |  Month Day Year**Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.** |
| 1. **Drugs ever used for MDR TB treatment, from MDR start date (select one option for each drug)**

**Duration of therapy is a CUMULATIVE time period and does not have to be consecutively given****Not Used**—**Drugs is/was not part of the MDR-TB treatment regimen****<1 month—Drug is/was part of the MDR-TB treatment regimen and was cumulatively taken for less than one (1) month****≥1 month—Drug is/was part of the MDR-TB treatment regimen and was cumulatively taken for greater than or each to one (1) month** |

|  |  |
| --- | --- |
| **Drug**  | **Length of Time Administered** (Not Used, <1 Month, ≥1 Month) |
| Isoniazid |  |
| Rifampin |  |
| Pyrazinamide |  |
| Ethambutol |  |
| Streptomycin\* |  |
| Rifabutin\* |  |
| Rifapentine\* |  |
| Amikacin\* |  |
| Kanamycin\* |  |
| Capreomycin\* |  |
| Ciprofloxacin\* |  |
| Ethionamide\* |  |
| Levofloxacin\* |  |
| Ofloxacin\* |  |
| Moxifloxacin\* |  |
| Cycloserine\* |  |
| Para-Amino Salicylic Acid\* |  |
| Linezolid\* |  |
| Bedaquiline\* |  |
| Delamanid\* |  |
| Clofazimine\* |  |
| Pretomanid\* |  |
| Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |  |
| \* indicates second- or third-line medication for purpose of US surveillance |

|  |  |
| --- | --- |
| 1. **Date injectable medication was stopped**

**Date the patient ended the injectable medication**  |  Month Day Year**Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.****Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.** [ ]  Not applicable |
| 1. **Was surgery performed to treat MDR TB?**
 |  [ ]  Yes [ ]  No Date: \_\_\_\_\_\_\_\_\_\_ **Yes—Surgery was performed as part of the MDR-TB treatment for the current episode of MDR-TB. Biopsy to diagnose MDR-TB is not considered surgery to treatment MDR-TB. However, excisional biopsy for the treatment of extrapulmonary TB is considered surgical treatment for MDR-TB.****No—Surgery was not done for the purpose of treatment for the current episode of MDR-TB****Date**—**Date the patient had surgery for MDR-TB** |

|  |
| --- |
| 1. **SIDE EFFECTS**
 |
| **Side Effect**  | **Experienced?** (Yes, No, Unknown)**Yes—Side effect reported. Side effects should have been reported by the patient or documented in the medical record. Side effect that existed prior to MDR-TB medication start but exacerbated by the MDR-TB treatment leading to a MDR-TB medication discontinuation should be recorded as YES****No—Side effect not reported****Unknown—It is unknown whether the side effect was reported** | **When?** (During Treatment, At End of Treatment, Both)**During Treatment—Patient reported side effect only during treatment i.e., the side effect resolved when treatment was stopped****At the End of Treatment—Patient reported side effect only at the end of treatment, i.e., after the treatment was stopped****Both—Patient reported side effect during treatment and at the end** |
| Depression* **Prolonged feelings of sadness or dejection, or documentation of depression by provider**
 |  |  |
| Suicide Attempt or Ideation* **Suicidal attempt or ideation (thoughts or attempt to hurt oneself)**
 |  |  |
| Cardiac Abnormalities* **QTc>500 ms (confirmed by repeat ECG or documented “prolonged QTc”)**
* **Clinically significant ventricular arrhythmia**
 |  |  |
| Hearing Loss* **Subjective hearing loss or noticing the need to turn up the volume on phones or TVs**
* **Requiring the needs for hearing aid or intervention**
* **Adults: If enrolled in Monitoring Program (on a 1, 2, 3, 4, 6 and 8 kHz audiogram): Threshold shift of 15-25 dB averaged at 3 contiguous test frequencies in at least one ear**
* **Pediatric (on a 1, 2, 3, 4, 6 and 8 kHz audiogram): hearing loss sufficient to indicate therapeutic intervention, including hearing aids; threshold >20 dB at 3 kHz and above in at least one ear**
* **Speech-language services indicated**
 |  |  |
| Tinnitus* **Subjective ringing, buzzing, roaring or clicking sounds in the ears**
 |  |  |
| Vestibular Dysfunction* **Feeling that the world is revolving around the patient (objective vertigo) or the patient is revolving in space (subjective vertigo)**
* **Dizziness or imbalance**
 |  |  |
| Peripheral Neuropathy* **Feeling of tingling, numbness, pressure, cold, and warmth that are experienced in the absence of a stimulus**
* **Usually limited to the extremities**
 |  |  |
| Renal Dysfunction* **Change in baseline renal function or proteinuria**
 |  |  |
| Vision Change/Loss* **Can involve one or both eyes**
* **Change of baseline of vision acuity or color vision**
* **Optic nerve damage resulting in worsening vision or blindness not present at baseline**
 |  |  |
| Liver Toxicity* **Liver enzyme concentrations exceeding three times the upper limit of normal (>3x ULN) if associated with symptoms *or***
* **Liver enzymes concentration exceeding five times the upper limit of normal (>5x ULN) if the patient is asymptomatic**
 |  |  |
| Myalgia* **Muscle pain**
 |  |  |
| Arthralgia* **Joint pain. Reports of gout, tendonitis, or tendon rupture may also be marked here**
 |  |  |
| Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)* **Any additional side effect(s) not included above**
 |  |  |

**END OF MDR TB SUPPLEMENTAL**