



Directly Observed Therapy, Adherence, & Completion of Treatment

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Has the following disclosures to make:

- No conflict of interests
- No relevant financial relationships with any commercial companies pertaining to this activity





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Learning Objectives

By the end of this presentation, participants will be able to:

- **Describe** the purpose and principles of directly observed therapy (DOT) in tuberculosis treatment.
- **Identify** at least three patient, social, or system-level barriers that may affect TB treatment adherence.
- **Select** appropriate case-management interventions to address barriers to adherence.
- **Demonstrate** appropriate follow-up strategies for patients who miss doses or have interruptions in treatment.
- **Determine** when a patient has met criteria for completion of TB treatment and appropriately document the treatment outcome.



Importance of Case Managers

- Establish rapport
- Educate patients
- Assess adherence
- Identify barriers
- Coordinate services
- Monitor treatment
- Communicate with providers
- Follow up on missed doses
- Document interventions
- Support treatment completion

The goal:

Help the patient successfully complete treatment



Why TB Treatment Adherence Matters

- **Cure the individual patient**
- **Prevent relapse**
- **Reduce TB transmission**
- **Prevent development of drug resistance**
- **Protect families and communities**
- **Improve public health outcomes**



What Is Directly Observed Therapy?

Directly observed therapy is an approach in which a trained healthcare worker or other designated individual observes the patient taking TB medication and provides support throughout treatment.

DOT includes:

- Observation of medication administration
- Patient education
- Adherence assessment
- Monitoring
- Communication
- Documentation
- Problem-solving
- Support



Who Is Placed On DOT

Provide DOT:

1. Every patient with an ATS classification of 3 or 5 will be placed on DOT for the duration of treatment.
 - a) Daily therapy is recommended (either 5x/week or 7x/week).
 - b) DOT must be initiated as soon as possible, but no longer than one week of outpatient treatment initiation.
 - c) VDOT may be used by TB programs when patients are recommended for DOT.

If self-administration is needed temporarily to accommodate holidays, travel, or a patient moving out of Texas, programs may provide up to one month's worth of DOT packets. Any more than that should be pre-approved by the TB Unit. NOTE: the LHP may determine how many doses of self-administration will "count" towards completion of adequate therapy; however, DOT must be provided for at least 80% of the total treatment.



DOT Is More Than Observation

Every DOT encounter is an opportunity to:

ASSESS

How is the patient doing?

ASK

Are there barriers or concerns?

EDUCATE

Does the patient understand the treatment?

ADDRESS

What problems can we solve?

DOCUMENT

What happened during today's encounter?

ENCOURAGE

Recognize progress and reinforce success.



Patient-Centered DOT

Ask the patient:

- **What makes your treatment difficult?**
- **What concerns do you have?**
- **What would make treatment easier?**
- **What schedule works best for you?**
- **Who can support you?**
- **What changes have occurred since our last visit?**

Patient-centered care means:

Working WITH the patient rather than simply telling the patient what to do.



DOT Delivery

Delivery Options:

- In-person DOT
- Clinic-based DOT
- Community-based DOT
- Workplace or other agreed-upon locations
- Video DOT/vDOT
- Other approved approaches

Consider:

- Patient preference
- Safety
- Reliability
- Technology access
- Work/school schedule
- Transportation
- Program requirements



Treatment Interruptions

Life happens and treatment may be interrupted

- Elevated LFTs (liver enzymes)
- Uncontrolled vomiting (anti-emetic not helpful)
- GI tuberculosis
- Drug interactions
- Grief



Treatment Interruptions

When an interruption occurs, consider:

- **Treatment phase**
- **Duration of interruption**
- **Number of doses missed**
- **Regimen**
- **Disease characteristics**
- **Drug susceptibility results**
- **Reason for interruption**
- **Previous adherence**
- **Current clinical status**

Treatment interruptions require individualized assessment.



Recognizing Early Warning Signs

Watch for:

- **Increasing missed appointments**
- **Difficulty contacting the patient**
- **Changes in work/housing**
- **Medication concerns**
- **New side effects**
- **Decreased engagement**
- **Expressions of frustration**
- **Technology problems**



Why Patients Miss Doses

Patient Factors

- Side effects
- Forgetfulness
- Lack of understanding
- Mental health concerns
- Substance use
- Competing priorities

Social Factors

- Housing instability
- Transportation
- Employment
- Childcare
- Stigma
- Limited support

System Factors

- Scheduling
- Communication
- Access to medication
- Healthcare coordination
- Language barriers



Why Would YOU Miss Doses

PAMELA'S REASONS

- Look at all them pills!!
- Forgetfulness (little bit)
- Side effects

Rifampin

Agitation, bleeding

gums, blood in the urine or stools, bruising, chest tightness, confusion, cough, coughing or vomiting, blood, dark urine, darkening of the skin, decreased frequency or amount of urine, difficulty in breathing and swallowing, dizziness, fainting, fast heartbeat, fever with or without chills, general feeling of tiredness or weakness, headache, hives, hoarseness, hostility, increased blood pressure, increased thirst, irritability, light-colored stools, loss of appetite, lower back or side pain, mental depression, nausea, painful or difficult urination, persistent bleeding or oozing from puncture sites, mouth or nose, puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue, skin itching, rash, or redness, sores, ulcers, or white spots on the lips or in the mouth, stomach pain, swelling of the face, ankles, fingers, hands, or lower legs, unusual bleeding or bruising, unusual drowsiness, dullness, tiredness, weakness, or feeling of sluggishness, vomiting, weight gain, yellow eyes or skin

Ethambutol

Chills, pain and swelling of joints, especially big toe, ankle, or knee, tense, hot skin over affected joints, Blurred vision, eye pain, red-green color blindness, or any loss of vision (more common with high doses), fever, joint pain, numbness, tingling, burning pain, or weakness in hands or feet, skin rash, Abdominal pain, confusion, headache, loss of appetite, nausea and vomiting

Pyrazinamide

Loss of appetite, pain and swelling of joints, especially big toe, ankle, and knee, tense, hot skin over affected joints, unusual tiredness or weakness, yellow eyes or skin



Isoniazid

Clumsiness or unsteadiness, dark urine, loss of appetite, nausea or vomiting, numbness, tingling, burning, or pain in hands and feet, unusual tiredness or weakness, yellow eyes or skin

Activity: Identify the Barrier

Small-Group Activity

For each scenario, identify:

1. What is the barrier?
2. Is it primarily patient, social, or system-related?
3. What could the case manager do?

Scenario A:

A patient repeatedly misses morning DOT because she works an early shift.

Scenario B:

A patient stops attending because transportation to the clinic is unreliable.

Scenario C:

A patient does not want coworkers to know about the TB diagnosis.

Scenario D

A patient reports nausea after taking medication.



Overcoming Barriers

Barrier	Possible intervention
Work schedule	Adjust observation schedule/location when permitted
Transportation	Transportation assistance or alternative DOT approach
Side effects	Assess, educate, and communicate with clinical team
Stigma	Education, confidentiality, supportive counseling
Forgetfulness	Reminders and routine-building
Language	Qualified interpretation
Housing instability	Coordinate social services



Communication Matters

Avoid judgmental questions:

“Why didn’t you take your medicine?”

Try:

“Tell me what happened.”

“What got in the way?”

“What concerns do you have?”

“What would make this easier?”

“How can we work together on this?”

Use:

Curiosity + empathy + problem-solving



Motivational Conversations

Helpful strategies:

- **Ask open-ended questions**
- **Listen before giving advice**
- **Reflect the patient's concerns**
- **Affirm progress**
- **Identify the patient's goals**
- **Collaboratively develop solutions**



When a Dose Is Missed

Step 1

- Identify the missed dose
- Was a dose actually missed?

Step 2

- Contact the patient promptly

Step 3

- Determine cause of missed dose

Step 4

- Assess for additional barriers



When a Dose Is Missed cont.

Step 5

- Develop a prevention plan

Step 6

- Document the event and intervention

Step 7

- Follow up with team members



What NOT to Do

Do not automatically:

- Assume the patient is unwilling to adhere
- Blame or shame the patient
- Double doses without clinical direction
- Restart treatment without appropriate guidance
- Ignore isolated missed doses
- Wait until the end of treatment to address a pattern



Instead:

Assess → Communicate → Intervene → Document
→ Follow program guidance

Initiation Phase Interruption

2. When any **interruption occurs in the initial phase**, this applies:
 - a. If total initial phase treatment is not completed in 10 weeks, the treatment needs to be restarted. Contact licensed healthcare provider for instructions.
 - b. If any interruption of less than 14 *cumulative* days occurs *the treatment can continue*.
 - c. When any interruption of 14 or more *cumulative* days occurs in the initial phase of treatment for TB disease, the regimen will need to be restarted. Contact the licensed healthcare provider for instructions.
 - i. If treatment is interrupted for drug intolerances, the patient must be on an empiric regimen considered adequate (RIP [RIF, INH, PZA], RIE [RIF, INH, EMB], or RPE [RIF, PZA, EMB]) for doses to count towards completion of therapy.
 - ii. If susceptibilities are known and there is no resistance to INH, RIF, or a fluoroquinolone (FQN), either levofloxacin or moxifloxacin, then once the patient is on *both* INH *and* RIF, or RIF and a FQN, doses can count towards completion of therapy.



Continuation Phase Restart

3. When any **interruption occurs in the continuation phase***, this applies:
- Ideally 100% of doses should be completed. However, if a patient received $\geq 80\%$ of doses in the continuation phase **and** sputum was AFB smear negative on initial testing, additional treatment *may* not be necessary if adherence or other factors (e.g., safety concerns) make completing treatment difficult. Contact the licensed healthcare provider.
 - If a patient received $\geq 80\%$ of doses in the continuation phase **and** sputum was AFB smear positive on initial testing, continue therapy until all doses are complete.
 - If a patient received $< 80\%$ of required doses in continuation phase **and** missed *less than 3* months of total doses throughout the intensive and continuation phase, continue therapy until all doses (100% of doses) are complete. However, therapy may need to be restarted in the following scenarios:
 - A consecutive lapse of > 2 months occurred, or
 - Treatment cannot be completed with the required time frame outlined in section D: Completion of Therapy for Drug Susceptible TB Disease.

If a patient received $< 80\%$ of required doses in continuation phase **and** missed 3 months or more of total doses throughout the intensive and continuation phase, restart therapy.



Adult Weight-Based Dosing

Daily Dosing				
Weight (kg) <i>Based on estimated lean body weight</i> [¥]	Isoniazid* (INH) Dose, mg (mg/kg)	Rifampin** (RIF) Dose, mg (mg/kg)	Pyrazinamide (PZA) Dose, mg (mg/kg)	Ethambutol (EMB) Dose, mg (mg/kg)
40-55 kg	300 [†] mg (5mg/kg)	600 mg (10-20mg/kg [‡])	1,000 mg (18.2-25.0)	800 mg (14.5-20.0)
56-75 kg			1,500 mg (20.0-26.8)	1,200 mg (16.0-21.4)
76-90 kg			2,000 [†] mg (22.2-26.3)	1,600 [†] mg (17.8-21.1)
Thrice (3x) Weekly Dosing – <i>Consultation Required</i>				
Weight (kg) <i>Based on estimated lean body weight</i> [¥]	Isoniazid* (INH) Dose, mg (mg/kg)	Rifampin** (RIF) Dose, mg (mg/kg)	Pyrazinamide (PZA) Dose, mg (mg/kg)	Ethambutol (EMB) Dose, mg (mg/kg)
40-55 kg	900 [†] mg (15mg/kg)	600 mg (10-20mg/kg)	1,500 mg (27.3-37.5)	1,200 mg (21.8-30.0)
56-75 kg			2,500 mg (33.3-44.6)	2,000 mg (26.7-35.7)
76-90 kg			3,000 [†] mg (33.3-39.5)	2,400 [†] mg (26.7-31.6)

Let's Break it down to what the patients see

40-55kg 8 Pills
56-75kg 10 Pills
76-90kg 12 Pills

This is taken daily for the first 56 days. After completion of the intensive phase the PZA and EMB is discontinued.... Sometimes



Recommended Doses

	Intensive Phase		Continuation Phase				
Regimen	Drugs	Interval, Dose	Regimen	Drugs	Interval and Dose, Duration	Range of Total Doses (duration)	Comments
1	INH, RIF [†] , PZA*, EMB**	7 days/wk for 56 doses in 8 wks, or 5 days/wk for 40 doses in 8 weeks	1a	INH, RIF	If 6 months' total therapy: 7 days/wk for 126 doses in 18 wks or 5 days/wk for 90 doses in 18 wks	182-130 (26 weeks)	Preferred regimen for patients with newly diagnosed tuberculosis.
			1b		If 9 months' total therapy: 7 days/wk for 217 doses in 31 wks or 5 days/wk for 155 doses in 31 wks	273-195 (39 weeks)	
Medical Consultation is Required for Regimens 2 and 3, as Daily Dosing Is Preferred							
2	INH, RIF [†] , PZA*, EMB**	7 days/wk for 56 doses in 8 wks, or 5 days/wk for 40 doses in 8 weeks	2a	INH, RIF	If 6 months' total therapy: 3 times/wk [†] for 54 doses in 18 wks	110-94 (26 weeks)	May be considered in rare cases when daily DOT in the continuation phase is not possible.
			2b		If 9 months' total therapy: 3 times/wk [†] for 93 doses in 31 wks	149-133 (39 weeks)	
3 [†]	INH, RIF [†] , PZA*, EMB**	3 times weekly for 24 doses in 8 weeks	3a	INH, RIF	If 6 months' total therapy: 3 times/wk [†] for 54 doses in 18 wks	78 (26 weeks)	Use with caution in patients with HIV and/or cavitary or extensive disease.
			3b		If 9 months' total therapy: 3 times/wk [†] for 93 doses in 31 wks	117 (39 weeks)	

“Almost finished” is not the same as “completed.”

Total DOT Doses

Regimen*	Total DOT Doses For INITIAL PHASE Completion
1	7 days per week for 56 doses administered by DOT in 8 weeks, OR 5 days per week for 40 doses administered by DOT in 8 weeks
2	7 days per week for 56 doses administered by DOT in 8 weeks, OR 5 days per week for 40 doses administered by DOT in 8 weeks
3	3 times weekly for 24 doses administered by DOT in 8 weeks

Regimen*	Total DOT Doses For CONTINUATION PHASE Completion
1a	7 days per week for 126 doses administered by DOT in 18 weeks OR 5 days per week for 90 doses administered by DOT in 18 weeks
1b	7 days per week for 217 doses administered by DOT in 31 weeks, OR 5 days per week for 155 doses administered by DOT in 31 weeks
2a	3 times weekly for 54 doses administered by DOT in 18 weeks
2b	3 times weekly for 93 doses administered by DOT in 31 weeks
3a	3 times weekly for 54 doses administered by DOT in 18 weeks
3b	3 times weekly for 93 doses administered by DOT in 31 weeks

When to Restart

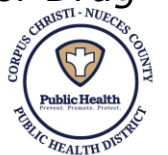
According to the Texas DSHS standing delegation orders 2026:

When any **interruption occurs in the initial phase**, this applies:

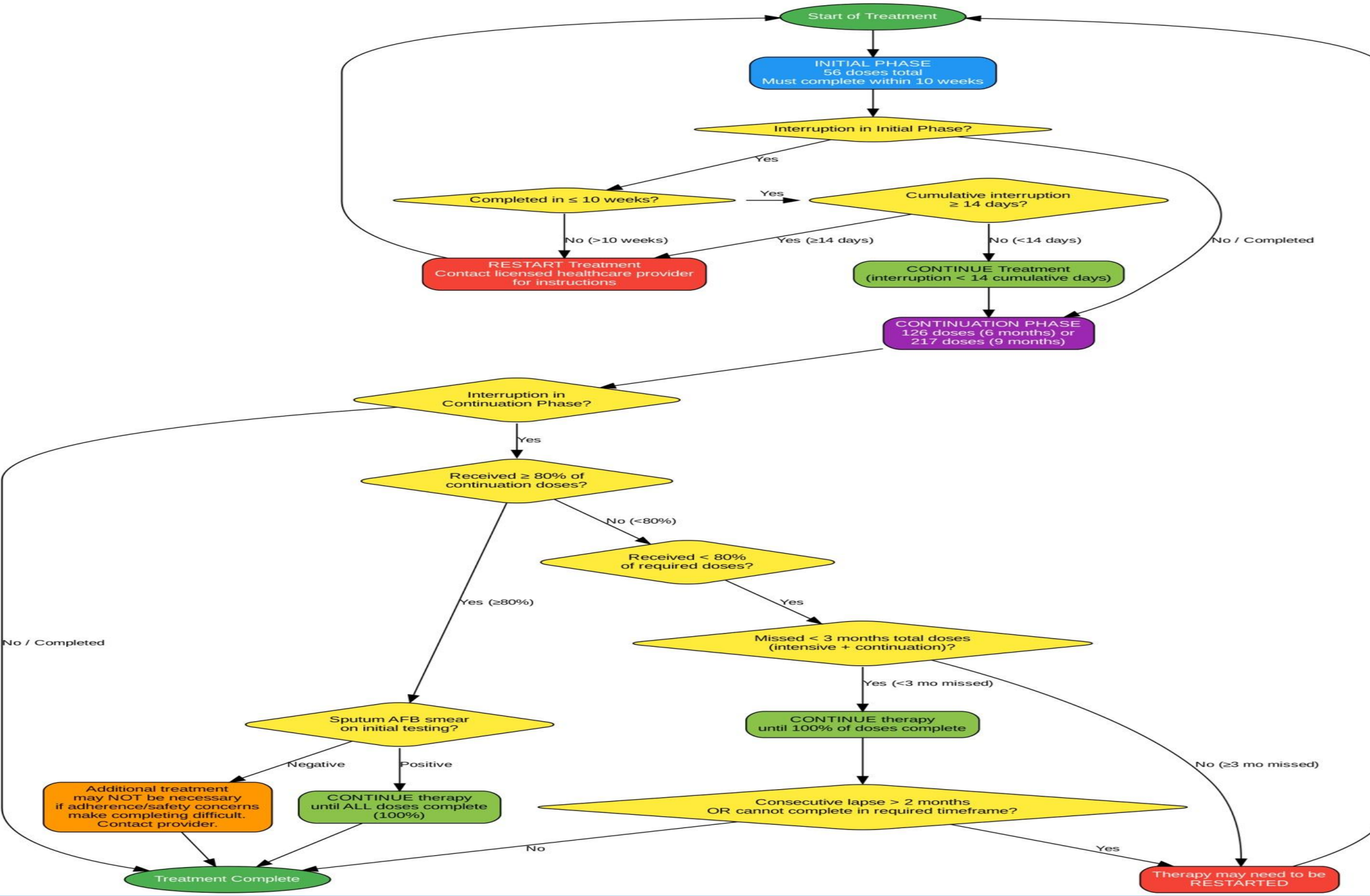
- If total initial phase treatment is not completed in 10 weeks, the treatment needs to be restarted. Contact licensed healthcare provider for instructions.
- If any interruption of less than 14 *cumulative* days occurs *the treatment can continue*.
- When any interruption of 14 or more *cumulative* days occurs in the initial phase of treatment for TB disease, the regimen will need to be restarted.

When any **interruption occurs in the continuation phase***, this applies:

- Ideally 100% of doses should be completed. However, if a patient received $\geq 80\%$ of doses in the continuation phase and sputum was AFB smear negative on initial testing, additional treatment *may* not be necessary if adherence or other factors (e.g., safety concerns) make completing treatment difficult. Contact the licensed healthcare provider.
- If a patient received $\geq 80\%$ of doses in the continuation phase and sputum was AFB smear positive on initial testing, continue therapy until all doses are complete.
- If a patient received $< 80\%$ of required doses in continuation phase and missed *less than* 3 months of total doses throughout the intensive and continuation phase, continue therapy until all doses (100% of doses) are complete. However, therapy may need to be restarted in the following scenarios:
 - A consecutive lapse of > 2 months occurred, or
 - Treatment cannot be completed with the required time frame outlined in section D: *Completion of Therapy for Drug Susceptible TB Disease*.



TB Disease Treatment: Phases & Interruption Guidelines
Initial Phase: 56 doses | Continuation: 126 (6 mo) or 217 (9 mo) doses



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Completion of Therapy for Drug Susceptible TB Disease

1. Completion of therapy for drug-susceptible TB disease by duration:

a. Six months (26 weeks) is generally the **minimum** duration of treatment.

- The 8-week intensive phase must be completed within 10 weeks.
- The 4-month continuation phase must be completed within 6 months.
- **Total 6-month regimen must be completed within 9 months.**

b. Nine months (39 weeks) is recommended for patients with cavitation on initial chest radiograph **and** positive cultures at completion of 2 months of therapy (see additional indications in #3, below), and for those patients intolerant of PZA or with *M. bovis* disease.

- The 8-week intensive phase must be completed within 10 weeks.
- The 7-month continuation phase must be completed within 9 months.
- **Total 9-month regimen must be completed within 12 months.**



Extrapulmonary

The following extrapulmonary TB sites generally require a longer duration of treatment:

- 1) Bone and joint: 9 months (39 weeks) of treatment recommended
- 2) Meningitis: 9 - 12 months (39 - 52 weeks) of treatment recommended
- 3) Disseminated/miliary TB: 9 - 12 months (39 - 52 weeks) of treatment recommended
- 4) Any site that is slow to respond should be considered for prolongation of treatment



NEDSS Update

Initiation Phase Start Date: 01/24/2025

Initiation Phase Stop Date: 03/21/2025

Number of Doses Administered During Initiation Phase: 56

Continuation Phase Start Date: 03/22/2025

Continuation Phase Stop Date: 08/06/2025

Number of Doses Administered During Continuation Phase: 131

	Medication Administered Month	Medication Administration Site	TB Medication Delivery Type	Number of Targeted Doses	Number of DOT (DOT/VDOT) Doses Taken (include dai	Number of SAT (SAT/ESAT) Doses Taken (Monthly)	Number of Missed Doses	Total Counted Doses This Month
	01/24/2025	Field (home, work, school, etc.)	Video DOT	8	8	0	0	8
	02/01/2025	Field (home, work, school, etc.)	Video DOT	28	28	0	0	28
	03/01/2025	Field (home, work, school, etc.)	Video DOT	31	28	0	3	28
	04/01/2025	Field (home, work, school, etc.)	Video DOT	30	29	1	0	30
	05/01/2025	Field (home, work, school, etc.)	Video DOT	31	30	0	1	30
	06/01/2025	Field (home, work, school, etc.)	Video DOT	30	30	0	0	30
	07/01/2025	Field (home, work, school, etc.)	Video DOT	31	27	0	4	27
	08/01/2025	Field (home, work, school, etc.)	Video DOT	6	6	0	0	6

End of Treatment Dose Counts

Total number of DOT/VDOT Doses: 187

Total number of SAT Doses: 0

Total Number of Doses Counted Towards Treatment Completion: 187

Total Number Recommended Doses: 182

Percent of Therapy Completed: 100

Percent of Therapy Completed via DOT/VDOT: 100



Has the Patient Completed Treatment?

Before documenting completion, confirm:

- Prescribed regimen requirements have been met
- Required doses have been administered
- Interruptions have been appropriately evaluated
- Monitoring requirements have been addressed
- Clinical team/program requirements have been met
- Treatment outcome is appropriate
- Documentation is complete



Knowledge Check #1

A patient repeatedly misses DOT because of a changing work schedule.

What is the best initial approach?

- A. Warn the patient that continued missed doses may result in court ordered TCID admission.**
- B. Ask about the scheduling barrier and work together to identify a feasible treatment-observation plan.**
- C. Document the missed doses and wait for the patient to contact the program.**



Knowledge Check #1 Answer

B: Ask about the scheduling barrier and work together to identify a feasible treatment-observation plan.

Why?

The case manager should first understand the barrier and work collaboratively toward a feasible solution.



Knowledge Check #2

A patient misses several doses of TB medication.

What should the case manager do?

- A. Tell the patient to double the next dose.**
- B. Ignore the missed doses if the patient feels well.**
- C. Determine the reason for the interruption, assess the circumstances, document the event, and follow TB program/clinical guidance.**
- D. Automatically restart the entire treatment regimen.**



Knowledge Check #2

Correct Answer:

C: Determine the reason for the interruption, assess the circumstances, document the event, and follow TB program/clinical guidance.



Knowledge Check #3

Which is an example of patient-centered adherence support?

- A. Requiring every patient to use the same DOT schedule.**
- B. Focusing only on whether medication was taken.**
- C. Identifying barriers and developing a treatment plan that addresses those barriers.**
- D. Waiting until the end of treatment to discuss adherence.**



Knowledge Check #3

Correct Answer:

C: Identifying barriers and developing a treatment plan that addresses those barriers.



Remember the 4 A's

ASSESS

Identify barriers early.

ADDRESS

Connect patients with appropriate support.

ADAPT

Make treatment support as patient-centered as possible.

ACHIEVE

Support the patient through completion.





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Thank you!

Questions?