## Evaluations for patients treated with a 4-month rifapentine-moxifloxacin TB treatment regimen



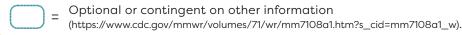








					Inten	sive F	Phase	a,b (Tot	al dos	es: 56)			Cont	inuat	tion P	hase	<sup>ı,c</sup> (Toto	ıl dose	s: 63)	
			Base- line	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10	WEEK <b>11</b>	WEEK <b>12</b>	WEEK <b>13</b>	WEEK <b>14</b>		week <b>16</b>	WEEK <b>17</b>
	Collect sputum sample	Acid-fast bacilli smear microscopy and culture <sup>d</sup>	х				Х				X				Xe					Xe
		Phenotypic drug-susceptibility test <sup>f</sup>	X				•				Xe				•					
		Rapid molecular test <sup>g</sup>	х																	
	Conduct chest radiograph	Chest radiograph <sup>h</sup>	x								Xe									Xe
\$ \$ € \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	Evaluate patient	Assess weight <sup>i</sup> , symptoms of TB disease <sup>j</sup> , current medications, and any patient co-morbidities and potential drug-drug interactions	x				X				X				X					x
	health	Review patient's clinical history, social determinants of health, and adverse drug reactions <sup>j</sup>	x				X				X				X					x
	Conduct laboratory testing	Alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, alkaline phosphate <sup>k</sup>	x				Xe				Xe				Xe					Xe
		Platelet count	х				Xe				Xe				Xe					Xe
		Creatinine	х				Xe				Xe				Xe					Xe
		Test blood levels of potassium, calcium, and magnesium	x				Хе				Xe				Xe					Xe
-		Pregnancy test <sup>m</sup>	х																	
		HIV test	х																	
		CD4 count, HIV viral load (if HIV-positive) <sup>n</sup>	Xe																	
		Hepatitis B and C screen°	Xe																	:
		Diabetes screen <sup>p</sup>	Xe																	
	Administer medication <sup>a,q</sup>	Rifapentine (RPT)		Х	Х	X	Х	Х	Х	Х	X	Х	Х	X	Х	Х	Х	Х	Х	Х
		Moxifloxacin (MOX)		X	X	X	X	X	X	Х	X	Х	X	X	X	X	X	X	X	Х
		Isoniazid (INH) <sup>r</sup>		X	X	X	X	X	X	Х	X	Х	X	X	X	X	Х	Х	Х	х
		Pyrazinamide (PZA)		X	X	X	X	X	X	Х	X									





Medication <sup>a,q</sup>	Body weight, kg	Dose per day, mg						
Rifapentine (RPT)	≥40	1200						
Moxifloxacin (MOX)	≥40	400						
Isoniazid (INH) <sup>r</sup>	≥40	300						
	40-<55	1000						
Pyrazinamide (PZA)	≥55-75	1500						
	>75	2000						



## Footnotes:

"At least 5 of 7 weekly doses should be administered under direct observation. Directly observed therapy means that a healthcare worker watches the TB patient swallow each dose of the prescribed drugs. The healthcare worker should ask the patient how he or she is feeling, check the medications before they are taken, ask the patient if he or she is experiencing any side effects, and answer any questions the patient may have. Where local policies allow, eDOT has been shown to be an acceptable alternative to traditional DOT. Contact your state or local TB control office for more information about eDOT policies and procedures (https://www.cdc.gov/tb/links/tboffices.htm).

<sup>b</sup>Must be administered completely within 70 days from treatment initiation. If this target is not met, the patient should be considered to have interrupted therapy and should be managed as described in TB treatment guidelines (https://academic.oup.com/cid/article/63/7/853/2197067).

<sup>c</sup>Must be administered within 84 days from intensive phase completion. If this target is not met, the patient should be considered to have interrupted therapy and should be managed as described in TB treatment guidelines (https://academic.oup.com/cid/article/63/7/853/2197067).

<sup>d</sup>Obtain sputa for acid-fast bacilli (AFB) smear and culture at baseline, then at least monthly until 2 consecutive specimens are smear and culture negative. For patients who have positive AFB smears at the time of diagnosis, follow-up smears may be obtained at more frequent intervals to provide an early assessment of the response to treatment, especially for patients in situations with high risk of transmission (https://academic.oup.com/cid/article/63/7/853/2197067)

eAdditional clinical information should be considered in timing and frequency of implementing this element (https://www.cdc.gov/mmwr/volumes/71/wr/mm7108a1.htm?s\_cid=mm7108a1\_w).

<sup>f</sup>Drug susceptibility at least for INH, RIF, PZA, and fluoroquinolones (preferred fluoroquinolone is moxifloxacin) should be obtained. Repeat drug susceptibility testing (rapid molecular preferred) if patient's culture remains positive after completing 2 months (8 weeks) of treatment.

<sup>9</sup>Baseline molecular drug-susceptibility testing of at least one baseline specimen for rapid identification of mutations associated with resistance to at least rifampin (RIF), isoniazid (INH), pyrazinamide (PZA), and fluoroquinolones is advisable.

<sup>h</sup>Obtain chest radiograph at baseline for all patients and also at month 2 if baseline cultures are negative. End-of-treatment chest radiograph is optional. Electrocardiogram (ECG) is not routinely recommended for all patients; it should be done if clinically indicated.

'Monitor weight monthly to assess response to treatment; adjust pyrazinamide dose if needed.

<sup>j</sup>Assess adherence and monitor improvement in TB symptoms (e.g., cough, fever, fatigue, night sweats) as well as development of medication adverse effects (e.g., jaundice, dark urine, nausea, vomiting, abdominal pain, diarrhea, anorexia, dizziness, seizures, fever, rash, malaise, neuropathy, arthralgias, tendinopathy, heart palpitations, irregular heartbeat, weakness, syncope).

<sup>k</sup>Liver function tests (LFTs) only at baseline unless abnormalities at baseline, symptoms consistent with hepatotoxicity develop, or for patients who chronically consume alcohol, take other potentially hepatotoxic medications, or have viral hepatitis or history of liver disease, HIV infection, or prior drug-induced liver injury.

Further monitoring if there are baseline abnormalities or as clinically indicated.

<sup>m</sup>People of child-bearing potential should be advised that rifapentine can reduce effectiveness of oral contraceptives and to practice barrier contraception method or non-hormonal intrauterine device or abstain from heterosexual intercourse during treatment.

"HIV testing in all patients. CD4 lymphocyte count and HIV viral load if positive.

°Hepatitis screening for all patients per CDC guidelines (https://www.cdc.gov/mmwr/volumes/69/rr/rr6902a1.htm). Patients with hepatitis B or C risk factors or elevated baseline LFTs should be tested for these viruses.

PFasting glucose or hemoglobin A1c for patients with risk factors for diabetes according to the American Diabetes Association, including: age >45 years, body mass index >25 kg/m2, first-degree relative with diabetes, and race/ethnicity of African American, Asian, Hispanic, American Indian/Alaska Native, or Hawaiian Native/Pacific Islander (https://professional.diabetes.org/content-page/practice-guidelines-resources). For patients with diabetes, glucose monitoring is indicated.

<sup>q</sup>Drugs are administered with food once a day, every day of the week.

'Pyridoxine (vitamin B6) 25-50 mg/day, should be given with isoniazid to all patients.