BPaLM & BPal Regimen
JOB AID

Overview

- The BPaLM & BPaL regimen are new and short all oral medication for DRTB.
- **BPaLM** is the preferred choice for Rifampicin Resistance TB (**RR-TB**) and/or resistant to both Rifampicin and Isoniazid (MDR-TB). The duration is **6-9 months**.
- **BPaL** is the regimen of choice for pre-XDR TB (pre-extensively drug-resistant TB). Preferred choice when there is **fluoroquinolone (FQ) resistant + MDR**. Its duration is **6-9 months**.

Theme	BPaLM	BPaL
Medicines in each	Bedaquiline - **BDQ** Pretomanid - **Pa** Linezolid - **Lzd** Moxifloxacin – **Mfx**	Bedaquiline - **BDQ** Pretomanid - **Pa** Linezolid - **Lzd**
Indication for use	The preferred regimen for RR-TB and MDR patients	The preferred regimen for Pre XDR TB
Duration of treatment	6-9 months	6 - 9 months (26 -39 weeks)
	The standard treatment duration is 6 months. If the sputum culture test is still positive after the patient has taken 4 months of treatment, the patient can receive an additional 3 months of treatment (total 9 months) if the patient is clinically well and /or improving.	

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Theme	BPaLM	BPaL
Eligible patients	Adults and adolescents aged 14 years and older with: - MDR/RR-TB - PTB and EPTB except TB involving CNS, osteoarticular, and disseminated (miliary) TB - HIV Coinfection - Not pregnant or Breastfeeding and on effective contraception or post-menopausal - Less than 1-month previous exposure to Bedaquilline, linezolid, pretomanid, or delamanid - For exposure longer than one month, use the regimen if resistance to specific medicines has been ruled out	Adults and adolescents aged 14 years and older with: - A laboratory-confirmed resistance to at least rifampicin & fluoroquinolones; or - strong clinical and radiological evidence of active TB and is a close household contact of a TB patient with a laboratory-confirmed resistance to at least rifampicin and fluoroquinolones; or - Treated MDR/RR-TB and has documented non-response to treatment, and the Expert Committee has decided to shift the patient to the BPaL regimen; or - Treated MDR-/RR-TB and has documented intolerance and a decision has been made by the Expert Committee to shift the patient to the BPaL regimen
	NOTE: DR-TB patients with severe forms (disease) of RR/MDR-TB &/or Pre-XDR-TB will be placed on longer all oral regimen or individualized regimes in consultation with the team of DR-TB experts	

Theme	BPaLM	BPaL
Ineligible patients	- Patients with additional Fluoroquinolone (FQ) resistance - known severe allergy to any of the BPaL component drugs; or - Has been previously exposed to any of the component drugs or delamanid (Dlm) for more than one month; or - Has a form of extrapulmonary TB that would require treatment longer than would be usual for pulmonary TB (e.g., TB meningitis, other central nervous system TB, or TB osteomyelitis, disseminated TB); or - Is pregnant or breastfeeding; or - Children and Adolescents less than 14 years - Is unable to take oral medications.	- Patients with a DST result showing resistance to any of the component drugs. - known severe allergy to any of the BPaL drugs. - Has been previously exposed to any of the component drugs or delamanid (Dlm) for more than one month; or - Has a form of extrapulmonary TB that would require treatment longer than would be usual for pulmonary TB (e.g., TB meningitis, other central nervous system TB, or TB osteomyelitis, disseminated TB); or - Is pregnant or breastfeeding; or - Children and Adolescents less than 14 years - Is unable to take oral medications.
Doses	**Bedaquiline** - 400 mg once daily for 2 weeks, then 200 mg thrice weekly. **Pretomanid** - 200 mg once daily. **Linezolid** - 600 mg once daily **Moxifloxacin** - 400 mg once daily	Bedaquiline - 400 mg once daily for 2 weeks, then 200 mg thrice weekly. Pretomanid - 200 mg once daily. Linezolid 600 mg once daily

BASELINE TESTS

- **Commence** patients on treatment same day if eligible (results of hemoglobulin **is greater than 8g/dL (PCV > 24%)** or a **platelet count greater than 75000/mm3)** after taking baseline tests while waiting for other baseline test results
- Ensure strict adherence of all healthcare providers to national standards.

ADVERSE EVENTS

Bedaquiline	Hepatotoxicity, QT Prolongation – all patients must have ECG at baseline and as prescribed for follow-up.
Pretonamid	Hepatotoxicity, QT prolongation, safety in pregnancy and breastfeeding mothers - not yet determined
Moxifloxacin	GIT, Rash, QT prolongation, arthralgia
Linezolid	Peripheral Neuropathy, Anemia, blurred vision Care should be taken for patients who have a haemoglobin level of less than 8g/dL or a platelet count less than 75000/mm^3

DRUG INTERACTION

- For HIV coinfection – HCWs must avoid Efavirenz-based ART regimen
- Avoid drugs that prolong QT – tricyclic antidepressants, clarithromycin, chlorpromazine, etc.

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