LIFT-TB Philippines
Leveraging Innovation for Faster Treatment of Tuberculosis
Introducing the BPaL Regimen under Operational Research

In collaboration with the National Tuberculosis Control Program (NTP) – Department of Health (DOH)

Tropical Disease Foundation, Inc.

ACCEPTABLE BPAL REGIMEN MODIFICATIONS UNDER OPERATIONAL RESEARCH

A. Linezolid (Lzd)

- The starting dose of Lzd should be 1200 mg daily given for at least the first four weeks of treatment. This may be reduced to 600 mg daily during the first 4 weeks of treatment, but must then be given for at least 9 weeks.
- Lzd dose is allowed to be further reduced below 600 mg daily, or temporarily or permanently stopped (while Bdq and Pa are continued) only after a patient has received:
  - at least **4 weeks of Lzd 1200 mg daily**
    OR
  - at least **9 weeks of Lzd 600 mg daily** (if the dose was reduced)
- Any modification of the Lzd dosage needs to be discussed with the TB Medical Advisory Committee (TB MAC).
- Any interruption of Lzd during the first 4 weeks of 1200 mg daily or within the first 9 weeks of 600 mg daily will warrant a switch to another regimen with advice from the TB MAC.
- Any dose reduction of Lzd lower than 600 mg daily, or interruption should have evidence of clinical and radiological improvement at least after the first 4 weeks of treatment, and should be followed by a careful clinical assessment to observe and manage the effect accordingly.
- Missed doses of Lzd alone are not to be made up at the end of treatment.

B. FULL BPaL regimen

- If an AE occurs that does not require modification of Lzd alone, but of the other component drugs (bedaquiline or pretomanid), then the FULL BPaL REGIMEN may be interrupted at any time during the treatment period:
  - **during** the first four weeks of treatment for a maximum of 14 days consecutively or non-consecutively
  - **after** the first four weeks of treatment for a maximum of 35 days consecutively or non-consecutively
- If the FULL BPaL regimen interruption is >14 days during the first 4 weeks or >35 days after the first 4 weeks, then the patient should be referred to the TBMAC to decide on further management, including the need to shift to an alternative regimen.
- After interruption, the **FULL BPaL regimen** may be restarted, including Lzd 1200 mg daily or 600 mg daily if the dose had to be reduced.
- Any missed doses of the full BPaL regimen (consecutive and non-consecutive) should be made up at the end of the treatment to complete 26 weeks or 39 weeks **within a maximum period of 60 days** after the intended end of treatment.

C. Bedaquiline (Bdq) and/or Pretomanid (Pa)
• No dose modifications are allowed for both Bdq and Pa at any time during the BPaL treatment (only dose modifications of Lzd are allowed, following specified conditions above). The doses of Bdq and Pa are fixed (except for the routine reduction of Bdq 400 mg daily to 200 mg thrice weekly after the first 14 days of treatment, or as indicated in the guide for Bdq loading dose).
• No interruption of Bdq or Pa alone is allowed. If Bdq or Pa needs to be interrupted, then the full BPaL regimen must be interrupted at once following the guidance on the modification of the BPaL regimen.
• No permanent discontinuation of Bdq or Pa is allowed. If Bdq or Pa needs to be discontinued, then the full BPaL regimen must be discontinued, the patient referred to TBMAC, and then switched to an alternative regimen.
• Pa should not be used outside the BPaL treatment regimen (unless recommended by WHO).

Any dose modification or regimen interruption and discontinuation should be discussed in advance preferably within 1-2 days with the TBMAC, and prior to the modification of treatment.