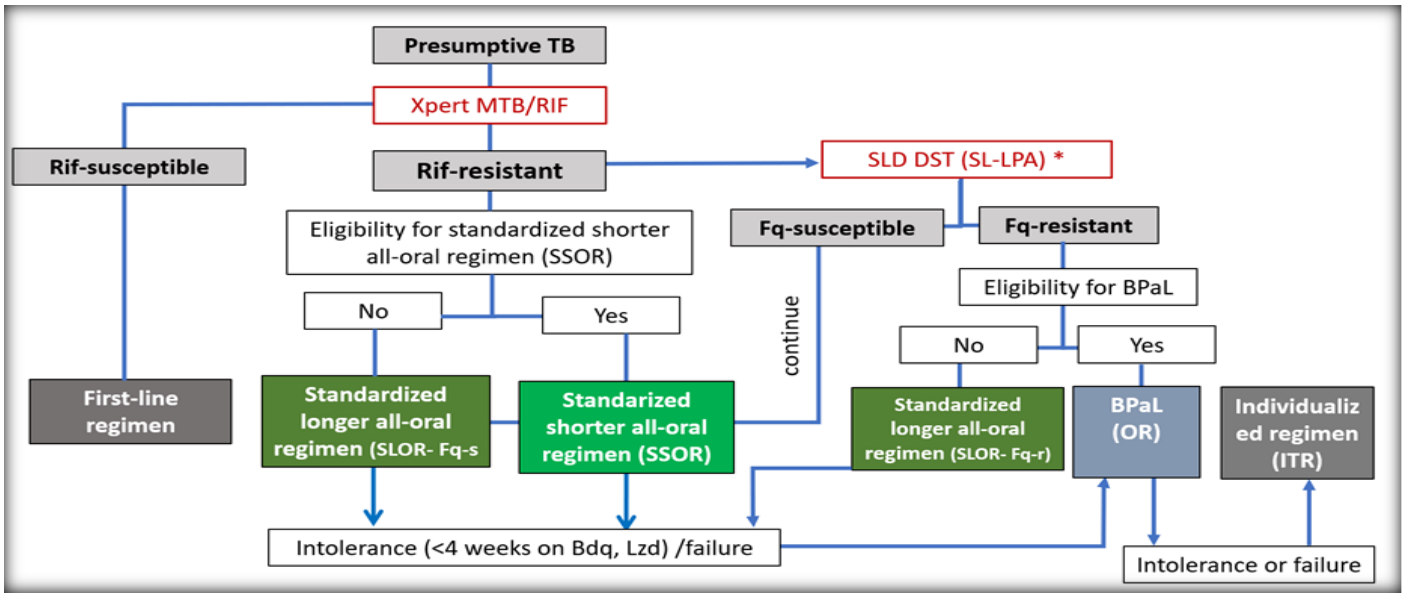
# LIFT-TB Philippines

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.




BPAL ALGORITHM

BPAL PATIENT RECRUITMENT AND SELECTION

## INCLUSION CRITERIA

1. ***M. tb*** **patient with a laboratory-confirmed (rapid and/or phenotypic DST) resistance to at least rifampicin and fluoroquinolone (FQ) within the last three months* of the screening date; OR**
2. **Patient has a strong clinical and radiological evidence of active TB AND has been a close household contact of an index patient with:**
   - ⇒ **active laboratory-confirmed resistant TB to at least rifampicin and FQ within the last three months* of the screening date AND**
   - ⇒ **no documented resistance to any of the BPaL component drugs (Bdq, Pa, Lzd) within the last three months * of the screening date; OR**
3. **Patient has documented non-response** to MDR/RR-TB treatment, and has bacteriologically confirmed active TB within the last three months* of the screening date and a decision has been made by the TBMAC to shift the patient to the BPaL regimen ; OR**
4. **Patient has documented intolerance*** to MDR/RR-TB treatment, and has bacteriologically confirmed active TB within the last three months* of the screening date and a decision has been made by the TBMAC to shift the patient to the BPaL regimen.**

**Any of the above AND**

- ⇒ **Patient is willing and able to give informed assent or consent (signed or witnessed consent, if illiterate) to be enrolled in the OR and adhere to the OR procedures including the follow-up schedule; AND**
- ⇒ **Patient is at least 18 years old at the time of enrolment.**

** Otherwise do Xpert testing and SL-LPA before enrolment to the study*

*** Non-response: a) 2 consecutive positive cultures of sputum samples collected after the end of the 2nd month (30 days apart) or treatment with lack of clinical improvement or with deterioration; or b) treatment outcome of "failure" according to WHO definition.*

**** Intolerance: inability to continue the second-line MDR/RR-TB regimen due to a documented adverse event*

**Relative indications needing TB MAC recommendation for inclusion in the BPaL OR as long as any of the above inclusion criteria is fulfilled:**

- ⇒ **Is 14-17 years old at the time of enrolment**
- ⇒ **Has a mild form of extrapulmonary TB with or without pulmonary TB**

## EXCLUSION CRITERIA

1. Known severe allergy to any of the BPaL component drugs; or
2. DST showing resistance to any of the BPaL component drugs; or
3. Previous exposure to any of the BPaL component drugs or Dlm >4 weeks; or
4. Known severe adverse event associated with any of the BPaL component drugs; or
5. Extrapulmonary TB that would require treatment longer than usual for pulmonary TB, e.g., TB meningitis, other central nervous system TB, or TB osteomyelitis; or
6. Inability to take oral medications; or
7. Body weight of <35 kg; or
8. Pregnancy; or plan to conceive within the next year; or
9. Childbearing ability and reluctance for effective contraception while on the BPaL treatment; or
10. Breastfeeding; or
11. TB MAC decision that it is not in the best interest of the patient to be enrolled in the BPaL OR due to the need of an individualized treatment regimen.

**The BPaL Operational Research (OR)** is a prospective cohort study using the regimen consisting of Bedaquiline (Bdq), Pretomanid (Pa) and Linezolid (Lzd).

In 2015-2017, the Nix-TB study showed that the BPaL regimen had a relapse-free cure in 98 (90%) among 109 XDR-TB patients, intolerant and non-responsive MDR-TB patients. https://www.nejm.org/doi/full/10.1056/NEJMoa1901814

Pretomanid (Pa) was approved in August 2019 by the US FDA, and in March 2020, by the European Medicines Agency (EMA) for the treatment of pulmonary XDR-TB or treatment-intolerant or non-responsive MDR-TB patients, in combination with Bdq and Lzd.

In June 2020, the WHO recommended the use of BPaL under OR in MDR/RR-TB patients resistant to FQ with no exposure to Bdq and Lzd or with exposure for no more than two weeks.

**The LIFT-TB Project**, funded by KOICA, is an initiative of the TB Alliance in collaboration with the KNCV Tuberculosis Foundation and the International Tuberculosis Research Center. It was launched in the Philippines in December 2020 with local support from the Tropical Disease Foundation. This study is endorsed and led by the Department of Health.

# CONTACT US

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KOICA Korea International Cooperation Agency

TB Alliance

International Tuberculosis Research Center

KNCV TUBERCULOSISFOUNDATION