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भारत सरकार
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स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & Family Welfare
निर्माण भवन, नई दिल्ली-110011
Nirman Bhavan, New Delhi-110011

Date :.....04/05/2021.....

DO No. Z-28015/142/2017-TB

Subject:- Policy decision on usage of Dlm(Delamanid) / Bdq (Bedaqualin) in management of longer oral MDR/XDR-TB regimen in patients in the age group of >5 years to 18 years

Dear All,

In line with the global recommendations, in consultation with the National Technical Experts Group (NTEG) on Pediatric TB, clearance by CDSCO & approval by competent authority, following policy decisions have been taken-

Existing policy	New decisions for implementation.
<ul style="list-style-type: none"> Use of Delamanid in >5-18 yrs as a part of longer oral regimen. (18-20 mth) Dlm(6) LfxLzd# Cfz Cs 	<ul style="list-style-type: none"> Bedaquiline to replace Delamanid in Longer oral MDR/XDR-TB regimen in eligible patients of >5 yrs (weighing at least 15 kg) to 18 yrs age group. Rest of the regimen will remain same (18-20) Bdq(6 month or longer) Lfx Lzd# Cfz Cs
<ul style="list-style-type: none"> No policy- about Dlm as first choice for replacement in regimen (18-20) Bdq (6 month or longer) Lfx Lzd# Cfz Cs. 	<ul style="list-style-type: none"> (18-20) Bdq(6 month or longer) Lfx Lzd# Cfz Cs, If, appropriate regimen cannot be designed using all 5 drugs from Group A and B due to high background resistance, non-availability or unreliability of DST then <ul style="list-style-type: none"> Dlm is first choice of replacement as per the replacement sequence from grp C, Combined use of Bdq and Dlm in all oral longer regimen for M/XDR-TB patients is allowed as per recommendation of local DRTB committee.
<ul style="list-style-type: none"> No policy-about extension of Bdq beyond 6 mth in >5-18 years age group 	<ul style="list-style-type: none"> (18-20) Bdq(6 month or longer) Lfx Lzd# Cfz Cs Extension beyond 6 months is to be considered in patients in whom an effective regimen cannot otherwise be designed if- <ul style="list-style-type: none"> only 2 of 5 drugs are available from Groups A & B due to high background resistance, non-availability or unreliability of DST and adequate number of Group C drugs are not available due to high background resistance, non-availability or unreliability of DST.

(May pls refer new revised guideline PMDT 2021)

[Signature]

Contd-on-2-
P.T.O.

टीबी हारेगा, देश जीतेगा

2. BDQ Tab formulation for use-

a) for child upto 8yr of age or 24kg of weight, the Child-friendly (i.e. dispersible and palatable) formulations of the Bdq, may be used **whenever available**. Meanwhile till the dispersible medicines are not available, the adult type of formulation may be dissolved in water with dosages as per body weight for usage in such patients.

b) for child > 8yr of age or >24kg of weight-are to be managed with adult type of formulation of Bdq.

3. Existing patients in the age group of >5 years to 18 years **who are already initiated on Delamanid containing regimen are not be shifted to Bedaquiline containing regimen** in between the course of treatment and **will complete DLM containing regimen**.

4 All the patients on newer drugs (Bdq/Dlm) are expected to be followed up as per the "Guidelines for PMDT in India - 2021" for monitoring the drugs' safety parameters and information need to be provided in the prescribed ADSM formats on a regular basis

Accordingly, states are requested to implement these decisions with immediate effect and to send their requirement of Bedaquiline courses based on the estimated eligible MDR/XDR TB patients $\geq 5 - 18$ years of age.

Yours Sincerely

(Dr. Sanjay Kumar)

To,

STO (All State & UT)

Copy for information:

1. PPS to Additional Secretary MoHFW, GoI
2. All officers and consultants, Central TB Division, MoHFW, GoI
3. WHO NPOs
4. WHO NTEP RTLs & Consultants