CLINICAL PRIORITIES ADVISORY GROUP
1 May 2024

Agenda Item No	2.1
National Programme	Blood and Infection
Clinical Reference Group	Infectious diseases
URN	2302

Title
Treatment for defined patients with RR-TB, MDR-TB, pre-XDR TB and XDR-TB including bedaquiline and delamanid (All Ages)

Actions Requested	1. Support the adoption of the policy proposition
	2. Recommend its approval as an IYSD

Proposition
Service delegation status – The drugs are the commissioning responsibility of Specialised Commissioning, the services that deliver them are an ICB commissioning responsibility. This is a proposition for an update to the existing clinical commissioning policy statement “Treatment for defined patients with MDR-TB and XDR-TB including bedaquiline and delamanid”. This proposed policy update has been undertaken by a Policy Working Group (PWG) consisting of TB experts, a public health specialist and specialised commissioner for NHS England. The 2024 update to this clinical commissioning policy statement covering the concurrent use of bedaquiline and delamanid is outside of the scope of the original independent evidence review conducted in 2019 and is based on clinical consensus in conjunction with the updated WHO 2022 guidelines. This proposed policy update retains the previous policy recommendation that bedaquiline and delamanid are available as treatment options for defined patients with MDR-TB and XDR-TB who meet the criteria outlined in the proposition. This proposed update to the clinical commissioning policy statement outlines the commissioning criteria for the use of concurrent use of bedaquiline and delamanid in adults and both sequential use and concurrent use of bedaquiline and delamanid in children. This proposition applies to the use of longer, individualised TB regimens in patients for whom a WHO recommended regimen cannot be constructed. Some of the recommendations sit outside of the current licenses for bedaquiline and delamanid but are supported by a number of studies and clinical consensus.

Clinical Panel recommendation
The Clinical Panel recommended that the policy statement proposition progress as a routine commissioning policy proposition.

The committee is asked to receive the following assurance:	
1.	The Deputy Director of Clinical Effectiveness confirms the proposition has completed the appropriate sequence of governance steps and includes a: Consensus Report; Clinical Panel Report.
2.	The Deputy Director of Acute Programmes confirms the proposition is supported by a: Rapid Impact Assessment; Engagement Report; Equality and Health Inequalities Impact Assessment; Clinical Policy Proposition. The relevant National Programme of Care has approved these reports.
3.	The Director of Finance (Specialised Commissioning) confirms that the rapid impact assessment has reasonably estimated a) the incremental cost and b) the budget impact of the proposal.
4.	The Director of Clinical Commissioning (Specialised Commissioning) confirms that the service and operational impacts have been completed.

The following documents are included (others available on request):	
1.	Clinical Policy Proposition
2.	Engagement Report
3.	Consensus Report
4.	Clinical Panel Report
5.	Equality and Health Inequalities Impact Assessment

Considerations from review by Rare Disease Advisory Group
Not applicable.

Pharmaceutical considerations
The Clinical Commissioning Policy Statement updates our commissioning position on the treatments for defined adults and children with rifampicin resistant (RR) tuberculosis (TB), multidrug-resistant (MDR) TB, pre-extensively drug-resistant (pre-XDR) TB and extensively drug-resistant (XDR-TB) including bedaquiline and delamanid, as described above. Bedaquiline is licensed for use as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis (MDR-TB) in adult and paediatric patients (5 years to less than 18 years of age and weighing at least 15 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability. The use of bedaquiline for >6 months and for paediatric patients <5 years old and weighing <15kg is off-label.

Delamanid is no longer licensed in the UK. The use of delamanid in line with the eligibility criteria in this proposition, is off-label. Where medicines are used off-label, Trust policy regarding unlicensed medicines should apply. Bedaquiline and delamanid are on the NHS Payment Scheme Annex A, that is, they are excluded drugs.

Considerations from review by National Programme of Care
The proposal received the full support of the Blood and Infection PoC on the 26th March 2024