NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 17th January 2024

Intervention: bedaquiline and delamanid treatment

Indication: for defined patients with RR-TB, MDR-TB, pre-XDR TB and XDR-TB

URN: 2317

Gateway: 2, Round 1

Programme: Blood and Infection

CRG: Infectious Diseases

Information provided to the Panel

Policy Statement Proposition

Change Form

Consensus Report

Equalities and Health Inequalities (EHIA) Assessment

Blueteq™ Form

Policy Working Group (PWG) Appendix

This Policy Statement Proposition recommends the option of concurrent use of bedaquiline and delamanid for patients aged ≥14 years with suspected, functional or confirmed rifampicin resistant (RR) tuberculosis (TB), multi-drug resistant (MDR) TB, pre-extensively drug resistant (pre-XDR) TB, or extensively drug resistant (XDR) TB.

NHS England has an existing, routinely commissioned, clinical commissioning policy statement for the treatment of defined patients with MDR- and XDR-TB which permits the sequential use of bedaquiline and delamanid. The original policy statement was supported by an independent evidence review. However, since the publication of that, the World Health Organisation (WHO) have updated their MDR-TB guidelines which now recognise that there is a subset of defined patients in whom bedaquiline and delamanid may be used concurrently when limited other treatment options are available, and if sufficient monitoring is in place. The existing policy statement has been updated based on clinical consensus to reflect the following:

- The eligible population for whom NHS England is the responsible commissioner via the incorporation of patients with RR-TB
- The updated WHO (2022) definitions of MDR-TB, pre-XDR-TB and XDR-TB
- The addition of the concurrent use of bedaquiline and delamanid as an additional treatment option in these defined patients
- The age of the individuals eligible for treatment with bedaquiline and delamanid in line with the updated WHO (2022) Information Notes on these drugs

All changes to the eligibility criteria within the proposition are reflected in the Consensus Report. All changes to the wider contextual information in the Clinical Commissioning Policy Statement are reflected in the Change Form.

The proposition and the supporting clinical consensus report were presented to Panel members. The proposed revisions were considered.

EHIA – no amendments requested.

Recommendation

Clinical Panel agreed with the proposition and recommended this proceeds as a routine commissioning proposition.

Why the panel made these recommendations

Panel members agreed with the recommended changes and endorsed the consensus methodology used to update the existing policy.

Documentation amendments required

Policy Proposition:

- Include ‘all ages’ in the title of the proposition.

Declarations of Interest of Panel Members: None received.

Panel Chair: Anthony Kessel, Deputy Medical Director, Specialised Services

Post panel amendments

Panel Comment	Amendment	Page Number
Policy Proposition		
Include ‘all ages’ in the title of the proposition.	Amended	All references to the title of the proposition have been amended.