



Final Appraisal Recommendation

Advice number: 2222 – October 2022

Bedaquiline (Sirturo®) 20 mg, 100 mg tablets

Submission by Janssen Cilag Ltd

Recommendation of the All Wales Medicines Strategy Group

Bedaquiline (Sirturo®) is recommended as an option for use within NHS Wales as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis (MDR-TB) in adults 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.

Additional note(s):

- AWMSG considered bedaquiline (Sirturo®) as an ultra-orphan medicine according to the criteria in the AWMSG appraisal process for a medicine for a rare disease.
- This advice incorporates and replaces the existing AWMSG recommendation on bedaquiline (Sirturo®) for use as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis in adult and adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability (Advice number 0820, originally published September 2020).

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 4860), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

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