

**Final Appraisal Recommendation**

**Advice No: 0815 – March 2015**

**Bedaquiline (Sirturo<sup>®</sup>▼) 100 mg tablets**

**Submission by Janssen-Cilag Ltd**

**Recommendation of AWMMSG**

**Bedaquiline (Sirturo<sup>®</sup>▼) is recommended as an option for use within NHS Wales for use as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.**

**Additional note(s):**

- AWMMSG considered that bedaquiline (Sirturo<sup>®</sup>▼) satisfies the AWMMSG criteria for ultra-orphan drug status.

In reaching the above recommendation AWMMSG has taken account of the appraisal documentation prepared by the AWMMSG Secretariat (reference number 1334), which includes the AWMMSG 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.

Marketing authorisation holder on first issue	Janssen Cilag Ltd
Date of first issue	March 2015
Last reviewed	March 2018

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