All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Final Appraisal Recommendation

Advice No: 0613 – March 2013

Aztreonam lysine (Cayston®) 75 mg powder and solvent for nebuliser solution

Submission by Gilead Sciences Ltd

Recommendation of AWMSG

Aztreonam lysine (Cayston®) is recommended as an option for restricted use within NHS Wales. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

Aztreonam lysine (Cayston®) should be restricted for third-line use in the following subpopulation within its licensed indication for suppressive therapy of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis aged six years and older:

- **Patients in whom nebulised colistimethate sodium and nebulised tobramycin are not tolerated or are not providing satisfactory therapeutic benefit.**

Aztreonam lysine (Cayston®) is not recommended for use within NHS Wales outside of this subpopulation.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 1715), 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.

Marketing authorisation holder on first issue:	Gilead Sciences Ltd
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