Clinical Policy: Aztreonam (Cayston)
Reference Number: ERX.SPMN.78
Effective Date: 07/16
Last Review Date: 06/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that aztreonam for inhalation solution (Cayston®) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Cystic Fibrosis (CF) (must meet all):
      1. Age ≥ 7 years;
      2. Diagnosis of CF;
      3. Pseudomonas aeruginosa is present in recent cultures of the airways;
      4. Member has a contraindication to, or has failed a trial of, TOBI® inhalation solution or TOBI® Podhaler™; or antibiotic susceptibility testing indicates that aztreonam would be more effective than tobramycin;
      5. Therapeutic plan does NOT include concurrent or alternating use of Cayston with TOBI/TOBI Podhaler;
      6. Prescribed daily dose of Cayston does not exceed 225 mg aztreonam on a 28 days on/28 days off cycle.

   Approval duration: 6 months

B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy.

II. Continued Approval
   A. Cystic Fibrosis (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
      2. Therapeutic plan does NOT include concurrent or alternating use of Cayston with TOBI/TOBI Podhaler;
      3. Prescribed total daily dose of Cayston does not exceed 225 mg aztreonam on a 28 days on/28 days off cycle;
      4. Member continues to respond positively to Cayston therapy in one or more of the following areas: pulmonary function, quality of life, pulmonary exacerbations.

   Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
   2. Refer to ERX.SPMN.16 - Global Biopharm Policy.
Background

Description/Mechanism of Action:
The active ingredient in Cayston is aztreonam, a monobactam antibacterial. The monobactams are structurally different from beta-lactam antibiotics (e.g., penicillins, cephalosporins, carbapenems) due to a monocyclic nucleus. This nucleus contains several side chains; sulfonic acid in the 1-position activates the nucleus, an aminothiazolyl oxime side chain in the 3-position confers specificity for aerobic Gram-negative bacteria including Pseudomonas spp., and a methyl group in the 4-position enhances beta-lactamase stability.

Formulations:
A dose of Cayston consists of a 2 mL amber glass vial containing lyophilized aztreonam (75 mg) and lysine (46.7 mg), and a low-density polyethylene ampule containing 1 mL sterile diluent (0.17% sodium chloride). The reconstituted solution is for inhalation. The formulation contains no preservatives or arginine.

FDA Approved Indication:
Cayston is a monobactam antibacterial/inhalation solution indicated to:
- Improve respiratory symptoms in CF patients with Pseudomonas aeruginosa. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV₁ <25% or >75% predicted, or patients colonized with Burkholderia cepacia.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cayston and other antibacterial drugs, Cayston should be used only to treat patients with CF known to have Pseudomonas aeruginosa in the lungs.

Appendices

Appendix A: Abbreviation Key
CF: cystic fibrosis
FEV₁: forced expiratory volume in one second
FVC: forced vital capacity

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created.</td>
<td>05/16</td>
<td>06/16</td>
</tr>
</tbody>
</table>

References
Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2016 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.