

Pharmacy Policy Bulletin

Title: Aztreonam (Cayston®)

Policy #: FS.CLIN.100

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This pharmacy policy will be reviewed regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent

Aztreonam (Cayston®) is indicated to improve respiratory symptoms in cystic fibrosis patients with *Pseudomonas aeruginosa*.

The use of Aztreonam (Cayston®) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

Description:

Aztreonam (Cayston) is a monobactam antibiotic that binds to penicillin binding proteins of susceptible bacteria which leads to inhibition of bacterial cell wall synthesis and death of the cell.

Policy

Aztreonam (Cayston) is approved in patients 7 years of age or older when all of the following inclusion criteria are met:

- Documentation of a diagnosis of Cystic fibrosis
- Documentation of *Pseudomonas Aeruginosa* in the lungs
- Documentation of FEV1 that is 25% to 75% of predicted

Guidelines

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any products that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References

Cayston [package insert]. Foster City CA. Gilead Sciences. 2010

Cayston website. Available at www.cayston.com. Accessed October 27, 2011.

Facts and Comparisons Website [Cayston]. Available at www.factsandcomparisons.com. Accessed October 27, 2011.

Gilead's Cayston Picks up panel endorsement but not based on data. Available at www.thepinksheet.com. Accessed October 27, 2011.

Gilead Prices Cystic Fibrosis Drug Cayston at slight premium to competitor. Available at www.thepinksheet.com. Accessed October 27, 2011.

McCoy K, Quittner A, Oermann C, et al. Inhaled Aztreonam Lysine for chronic airway pseudomonas aeruginosa in cystic fibrosis. Am J Respir Crit Care Med. 2008; 178; 921-928.

Micromedex website [Cayston]. Available at www.micromedex.com. Accessed October 27, 2011.

NDA approval letter. Available at www.fda.gov. Accessed October 27, 2011.

Oermann C, Retsch-Bogart G, Quittner A, et al. An 18 month study of the safety and efficacy of repeated courses of inhaled Aztreonam Lysine in Cystic Fibrosis. Pediatric Pulmonology, 2010. 1-13.

Retsch-Bogart G, Quittner A, Gibson R, et al. Efficacy and Safety of inhaled Aztreonam lysine for airway pseudomonas in cystic fibrosis. Chest 2009; 135; 1223-1232.

Applicable Drugs

i Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Drug Name	Strength and/or formulation
Aztreonam (Cayston)	All

Cross References

Policy version number: 2.0
P&T approval date: 9/8/2011
Policy effective date: 12/1/2011
Next required review date: 9/8/2012

The Policy Bulletins on this website were developed to assist AmeriHealth in administering the provisions of the respective benefit programs, and do not constitute a contract. If you are an AmeriHealth member, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. AmeriHealth does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of AmeriHealth. If you have a specific medical condition, please consult with your doctor. AmeriHealth reserves the right at any time to change or update its Policy Bulletins. ©2011 AmeriHealth, Inc. All Rights Reserved.