

Clinical Policy: Aztreonam (Cayston)

Reference Number: CP.PHAR.209

Effective Date: 05.01.16

Last Review Date: 02.20

Line of Business: HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Aztreonam (Cayston[®]) is a monobactam antibacterial.

FDA Approved Indication(s)

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

Limitation(s) of use:

- Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with forced expiratory volume in one second (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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Cayston is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Cystic Fibrosis** (must meet all):

1. Diagnosis of CF;
2. Age ≥ 6 years;
3. *Pseudomonas aeruginosa* is present in at least one airway culture;
4. Member meets one of the following (a or b):
 - a. Failure of inhaled tobramycin (*TOBI[®]* and *TOBI[®] Podhaler[™]* are preferred) unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for inhaled tobramycin*
 - b. Antibiotic susceptibility testing indicates that aztreonam would be more effective than tobramycin;
5. If Cayston is prescribed concurrently (or for alternating use) with inhaled tobramycin (Bethkis[®], Kitabis Pak[®], TOBI, TOBI Podhaler), documentation supports inadequate response to either agent alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations);

6. Dose does not exceed 225 mg per day administered on a 28 days on/28 days off cycle.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Cystic Fibrosis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If Cayston is prescribed concurrently (or for alternating use) with inhaled tobramycin (Bethkis, Kitabis Pak, TOBI, TOBI Podhaler), documentation supports inadequate response to either agent alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations);
4. If request is for a dose increase, new dose does not exceed 225 mg per day administered on a 28 days on/28 days off cycle.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CF: cystic fibrosis

FDA: Food and Drug Administration

FEV₁: forced expiratory volume in one second

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
inhaled tobramycin (Bethkis, Kitabis Pak, TOBI, TOBI Podhaler)	Inhalation solution (Bethkis, Kitabis Pak, TOBI): 300 mg inhaled BID for 28 days (followed by 28 days off tobramycin therapy) Inhalation powder (TOBI Podhaler): 112 mg (4 capsules) inhaled BID for 28 days (followed by 28 days off tobramycin therapy)	Solution: 600 mg/day Powder: 224 mg/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known allergy
- Boxed warning(s): none reported

Appendix D: General Information

- Aztreonam is recommended for chronic use in both mild and moderate-to-severe disease per the American Thoracic Society 2013 CF guidelines. Severity of lung disease is defined by FEV₁ predicted as follows: normal, > 90% predicted; mildly impaired, 70-89% predicted; moderately impaired, 40-69% predicted; and severely impaired, < 40% predicted.
- The use of continuous alternating therapy (i.e., alternating different inhaled antibiotics in order to provide continuous therapy) lacks sufficient evidence. The efficacy of this practice was evaluated in a randomized, double-blind, phase 3 trial. 90 patients received 28-days inhaled tobramycin alternating with either 28-days inhaled aztreonam or placebo. Although the study found reduced exacerbation and respiratory hospitalization rates with the alternating tobramycin/aztreonam regimen compared to tobramycin/placebo, it was underpowered, and these results were not statistically significant.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CF	One dose (one single use vial and ampule of diluent) inhaled TID for 28 days (followed by 28 days off Cayston therapy)	225 mg/day

VI. Product Availability

Vial: 75 mg

VII. References

1. Cayston Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; February 2019. Available at www.cayston.com. Accessed October 28, 2019.

2. Flume PA, Mogayzel PJ, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: treatment of pulmonary exacerbations. Am J Respir Crit Care Med. 2009; 180: 802-808.
3. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013; 187(7): 680-689.
4. Flume PA, Clancy JP, Retsch-Bogart GZ, et al. Continuous alternating inhaled antibiotics for chronic pseudomonal infection in cystic fibrosis. J Cyst Fibrosis. 2016; 15(6): 809-815.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.54 CF Treatments. Concurrent use of Cayston with TOBI/TOBI Podhaler is restricted per 2015 expert review citing lack of evidence. Appendix C (clinical reasons to continue CF therapy) is replaced by “Member continues to respond positively to Cayston therapy in one or more of the following areas: pulmonary function, quality of life, pulmonary exacerbations”. Approval periods are extended from 3 to 6 and 6 to 12 months.	05.16	5.16
FEV1 delineation of $\leq 90\%$ added to initial criteria. Allergy contraindication removed. B. cepacia restriction removed as it is not a contraindication. Efficacy statement edited to indicate a general positive response to therapy.	05.17	05.17
1Q18 annual review: - Initial: Modified age restriction from ≥ 7 to ≥ 6 years per ATS guideline recommendations. Removed baseline FEV requirement. - Added allowance for concurrent/alternating use with tobramycin pending supportive documentation of inadequate response to either agent alone. - Added Appendix C: General Information -References reviewed updated.	10.27.17	02.18
1Q 2019 annual review: added HIM; no significant changes; references reviewed and updated.	10.17.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.28.19	02.20

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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