

Generic Name: Aztreonam

Therapeutic Class or Brand Name: Cayston

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 1600000540

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 5/30/2019

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

- I. Documented diagnosis of cystic fibrosis.
- II. Positive culture demonstrating *Pseudomonas aeruginosa* in the lungs.
- III. FEV₁ must be greater than 25% and less than 75% predicted.
- IV. Prescribed dose is 75mg TID to be administered in repeated cycles of 28 days on drug followed by 28 days off drug.
- V. Minimum age requirement: 7 years old.
- VI. The prescriber is a Pulmonologist or an Infectious Disease Specialist.

EXCLUSION CRITERIA

- Patients colonized with *Burkholderia cepacia*.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- One 28-day kit per 56 days.

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing positive clinical response (must have improved FEV₁ AND a decrease in the sputum density of *P. aeruginosa*).

APPENDIX

N/A

REFERENCES

1. Cystic Fibrosis Foundation. Chronic Medications to Maintain Lung Health Clinical Care Guidelines. Available at: <https://www.cff.org/Care/Clinical-Care-Guidelines/Respiratory-Clinical-Care-Guidelines/Chronic-Medications-to-Maintain-Lung-Health-Clinical-Care-Guidelines/>
2. Medi-Span.
3. Cayston® [Package insert] Foster City, CA: Gilead Sciences Inc; February 2019. Available at: http://www.gilead.com/~media/Files/pdfs/medicines/respiratory/cayston/cayston_pi.pdf.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
5/30/2019	1. Removed outdated references. Added " https://www.cff.org/Care/Clinical-Care-Guidelines/Respiratory-Clinical-Care-Guidelines/Chronic-Medications-to-Maintain-Lung-Health-Clinical-Care-Guidelines/ " under References .
9/25/2018	2. Removed " http://www.fchp.org/~media/Files/FCHP/Imported/Cayston_aztreonam.pdf.ashx ." Added " https://www.fchp.org/providers/pharmacy/~media/Files/FCHP/Imported/Cayston_aztreonam.ashx " under References . 3. Removed " https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/Notification_Cayston.pdf ." Added " https://www.uhcprovider.com/content/provider/en/viewer.html?file=%2Fcontent%2Fdam%2Fprovider%2Fdocs%2Fpublic%2Fprior-auth%2Fdrugs-pharmacy%2Fcommercial%2Fa-g%2FCOMM-Notification-Cayston.pdf " under References .
12/7/2017	1. Policy reviewed: no changes made.
9/26/2016	1. Removed " http://www.connecticare.com/provider/PDFs/Pharmacy/Cayston.pdf " from References (link no longer valid).
4/7/2015	1. Added "Prescribed dose is 75mg TID to be administered in repeated cycles of 28 days on drug followed by 28 days off drug" and "The prescriber is a Pulmonologist or an Infectious Disease Specialist" under Prior Authorization Criteria . 2. Changed "Dosing information: 75mg of Cayston® administered 3 times a day for a 28 day course, using an Altera Nebulizer System, followed by 28 days off Cayston®. A bronchodilator should be used before administration of Cayston®" to "N/A" under Other Criteria . 3. Updated " https://www.oxhp.com/secure/policy/aztreonam_for_inhalation_solution_cayston.pdf " to " https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-

	<p>US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/Notification_Cayston.pdf" under References.</p>
<p>11/26/2013</p>	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added GPI Code. 3. Changed "Documented diagnosis of <i>Pseudomonas aeruginosa</i> in the lungs" to "Positive culture demonstrating <i>Pseudomonas aeruginosa</i> in the lungs" under Prior Authorization Criteria. 4. Changed "FEV₁ must be greater than 25% or less than 75% predicted" to "FEV₁ must be greater than 25% and less than 75% predicted" under Prior Authorization Criteria. 5. Added "Patients colonized with <i>Burkholderia cepacia</i>" under Exclusion Criteria. 6. Changed "Usual dose" to "Dosing information" under Other Criteria. 7. Changed "1 28-day kit per month" to "One 28-day kit per 56 days" under Quantity/Days Supply Restrictions. 8. Changed Authorization under Approval Length from "1 month" to "6 months". 9. Updated references to include Connecticare and Oxford policies, Medi-Span, and updated website address for Cayston package insert.