Pharmacy Policy Bulletin: J-0216 Cuvposa (glycopyrrolate oral solution) – Commercial and Healthcare Reform	
Number: J-0216	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.)** **1.** Other Managed Drugs = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0216-008	**Original Date:** 05/01/2019
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Cuvposa (glycopyrrolate oral solution)
FDA-Approved Indication(s):	• To reduce chronic severe drooling in patients aged 3-16 years old with neurologic conditions associated with problem drooling (e.g., cerebral palsy).

Background:	• Cuvposa is a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues. Cuvposa has poor central nervous system penetration which may be preferred for the reduced likelihood of unfavorable centrally mediated side effects.
	• Prescribing Considerations:
	  ○ Cuvposa should not be used in patients with medical conditions that preclude anticholinergic therapy.
	  ○ Cuvposa should not be used concomitantly with solid oral dosage forms of potassium chloride.
	  ○ Maximum recommended dose is 0.1 mg/kg three times daily, not to exceed 1.5-3 mg per dose based upon weight.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Cuvposa (glycopyrrolate oral solution) may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member is between 3 and 16 years of age.

B. The member has a neurologic condition (e.g., cerebral palsy, mental retardation, stroke) associated with chronic, severe drooling (ICD-10 K11.7).

C. If the request is for brand Cuvposa, the member has experienced therapeutic failure or intolerance to generic glycopyrrolate oral solution.

II. Reauthorization

When a benefit, reauthorization of Cuvposa (glycopyrrolate oral solution) may be approved when the following criterion is met **(A. and B.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

B. If the request is for brand Cuvposa, the member has experienced therapeutic failure or intolerance to generic glycopyrrolate oral solution.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

Refer to J-0486 for previous versions of the Healthcare Reform policy.

References:

1. Cuvposa [package insert]. Raleigh, NC: Merz North America, Inc.; January 2023.
2. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics: 2024.