Original Effective Date: 12/01/2015
Current Effective Date: 06/28/2025
Last P&T Approval/Version: 04/30/2025
Next Review Due By: 04/2026
Policy Number: C8453-A

Cuvposa (glycopyrrolate) Oral Solution

PRODUCTS AFFECTED

Cuvposa (glycopyrrolate), glycopyrrolate soln

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Neurologic conditions associated with problem drooling (e.g., cerebral palsy)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. SEVERE DROOLING:
1. Member has a diagnosis of a neurologic condition associated with severe drooling
   AND
2. (a) Documentation of a trial (14 days) and failure or serious side effects to generic glycopyrrolate

tablets.
OR
(b) Documentation to support medical necessity of oral solution over oral tablets
AND

3. FOR BRAND NAME REQUESTS: Documentation of trial and failure of a generic AND Documentation the member experienced a documented adverse drug reaction with the generic agent (e.g., rash, anaphylaxis) that is NOT a known side effect of the medication and/or the prescriber has submitted a completed FDA MedWatch form [DOCUMENTATION REQUIRED]
AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Cuvposa (glycopyrrolate) include: medical conditions that preclude anticholinergic therapy, concomitant use of solid oral dosage forms of potassium chloride.]

CONTINUATION OF THERAPY:

A. SEVERE DROOLING:

1. Documentation of improvement of drooling symptoms while on therapy
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

No restriction

AGE RESTRICTIONS:

3 years of age and older

QUANTITY:

Dosed 0.02 mg/kg/dose orally three times daily. Titrate in 0.02 mg/kg/dose increments every 5 to 7 days based on efficacy and tolerance.
Max dose varies by weight.
Weight 13 to 17 kg = 1.5 mg/dose
Weight 18 to 22 kg = 2 mg/dose
Weight 23 to 27 kg = 2.5 mg/dose
Weight 28 kg or more = 3 mg/dose

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

DRUG CLASS:

Quaternary Anticholinergics

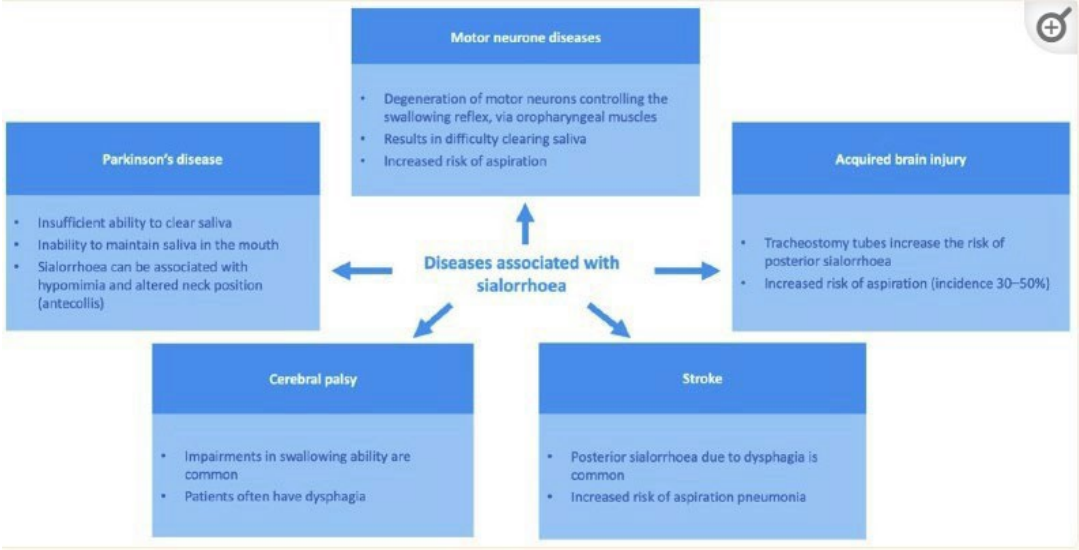
FDA-APPROVED USES:

Indicated to reduce chronic severe drooling in patients aged 3-16 years with neurologic conditions associated with problem drooling (e.g., cerebral palsy)

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Sialorrhoea is a frequent symptom of neurological diseases (e.g., Parkinson's disease, motor neuron disease, cerebral palsy, and stroke) and is defined as excessive saliva accumulation leading to unintentional loss of saliva from the mouth. Sialorrhoea increases the overall burden on the patient and their caregivers, the impact of which can be both physical and psychosocial. Treatments for sialorrhoea range from lifestyle and behavioral guidance, to medications, surgery or radiation. Nonpharmacological interventions include advice on posture, swallowing control, cough management, dietary changes, eating and drinking techniques, and behavioral modification; however, these conservative measures may be ineffective for people with progressive neurological conditions.



BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Glycopyrrolate is an antimuscarinic anticholinergic agent. Parenterally, glycopyrrolate is used as a preanesthetic and intraoperative antimuscarinic agent, where it helps block cardiac vagal inhibitory reflexes and helps reduce excessive salivary, tracheobronchial, and pharyngeal secretions. Since glycopyrrolate is a quaternary (i.e., charged) compound, it is less likely to penetrate the CNS and cause CNS side effects when compared to atropine or scopolamine. In addition, its charged status reduces oral bioavailability, and therefore, there is a significant difference between the oral and parenteral doses. Historically, oral and parenteral glycopyrrolate are indicated to treat and prevent peptic ulcers; however, due to availability of more effective alternatives for treatment, antimuscarinics have limited utility for this purpose. Oral products are commonly used today to reduce severe chronic drooling (sialorrhea) in patients 3 years and older with certain neurologic conditions. Glycopyrrolate inhalation power and nebulizer solution are also indicated for the long- term maintenance treatment of airflow obstruction in adults with chronic obstructive pulmonary disease (COPD).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Cuvposa (glycopyrrolate) oral solution are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindication to Cuvposa (glycopyrrolate) oral solution include: medical conditions that preclude anticholinergic therapy (e.g., closed-angle glaucoma, gastrointestinal bleeding, gastrointestinal obstruction, hemorrhagic shock, ileus, myasthenia gravis, toxic megacolon, ulcerative colitis, and urinary tract obstruction), and concomitant use of solid oral dosage forms of potassium chloride.

OTHER SPECIAL CONSIDERATIONS:

Drug and Biologic Coverage Criteria
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Cuvposa SOLN 1MG/5ML (473ml)
Glycopyrrolate SOLN 1MG/5ML (473mL)

REFERENCES

1. Cuvposa (glycopyrrolate) oral solution [prescribing information]. Raleigh, NC: Merz North America, Inc.; January 2023.
2. Buck ML. Glycopyrrolate Use in Children. Pediatr Pharm. 2010;6(12).
3. Evatt M. Oral Glycopyrrolate for the Treatment of Chronic Severe Drooling Caused by Neurological Disorders in Children. Neuropsych Disease and Treatment. 2011:7; 543-547.
4. Blasco PA,Stansbury, JC Glycopyrrolate Treatment of Chronic Drooling. Arch PediatrAdolesc Med. 1996 Sep; 150 (9); 932-5.
5. Tscheng DZ. Sialorrhea-Therapeutic Drug Options. Ann Pharmacother. 2002 Nov; 36 (11)1785-90.
6. Morgante F, Bavikatte G, Anwar F, Mohamed B. The burden of sialorrhoea in chronic neurological conditions: current treatment options and the role of incobotulinumtoxina (Xeomin®). Ther Adv Neurol Disord. 2019

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: References	Q2 2025
REVISION- Notable revisions: Required Medical Information References	Q2 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Appendix Contraindications/Exclusions/Discontinuation References	Q2 2023

REVISION- Notable revisions: Products Affected Available Dosage Forms	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file