**Original Effective Date: 12/01/2015**
**Current Effective Date: 05/31/2024**
**Last P&T Approval/Version: 04/24/2024**
**Next Review Due By: 04/2025**
**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:**

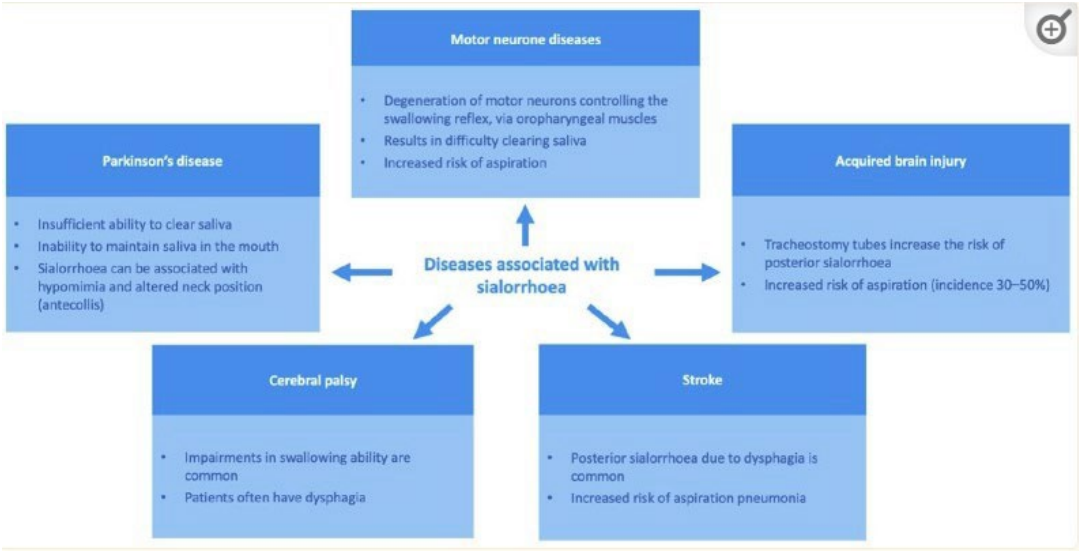
Indicated to reduce chronic severe drooling in patients aged 3-16 years with neurologic conditions associated

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:**
None

## CODING/BILLING INFORMATION

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

| HCPCS CODE | DESCRIPTION |
|---|---|
| NA | |

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

## REFERENCES


1. Cuvposa (glycopyrrolate) [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:<br>Required Medical Information<br>References | Q2 2024 |
| REVISION- Notable revisions:<br>Required Medical Information<br>Continuation of Therapy<br>Duration of Approval<br>Appendix<br>Contraindications/Exclusions/Discontinuation<br>References | Q2 2023 |
| REVISION- Notable revisions:<br>Products Affected<br>Available Dosage Forms | Q2 2022 |
| Q2 2022 Established tracking in new format | Historical changes on file |