Mass General Brigham
Health Plan

Glycopyrrolate Agents:
Cuvposa (glycopyrrolate oral solution)
Dartisla ODT (glycopyrrolate orally disintegrating tablet)
Glycate (glycopyrrolate 1.5mg tablet)
glycopyrrolate injection
Effective 09/01/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Glycopyrrolate is an anticholinergic agent, a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues including salivary glands.

Cuvposa (glycopyrrolate oral solution) is FDA-approved to reduce chronic severe drooling in patients 3 to 16 years of age with neurologic conditions associated with problems of drooling (e.g., cerebral palsy). Robinul (glycopyrrolate) injection was FDA-approved in 1975 for use as an adjunct for the treatment of peptic ulcer, as a preanesthetic agent to reduce secretions, and reversal of neuromuscular blockade. Dartisla ODT (glycopyrrolate) orally disintegrating tablets were FDA-approved in 2021 as an adjunct for the treatment of peptic ulcer disease.

No PA Required	Drugs that require PA
glycopyrrolate 1mg, 2mg tablet	Cuvposa® (glycopyrrolate oral solution) †
	Dartisla ODT (glycopyrrolate orally disintegrating tablet)
	Glycate® (glycopyrrolate 1.5mg tablet) *
	glycopyrrolate injection

* This is a branded-generic drug
†A-rated generic available. Brand and A-rated generic require a PA.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met:

Cuvposa (glycopyrrolate oral solution)
ALL of the following:

1. For members <17 years of age:
    a. The member has a neurologic condition associated with drooling (e.g. cerebral palsy, Rett syndrome, mental retardation, Parkinson's disease)
    b. Member's current weight to determine appropriate dosing
    c. Medical necessity for use of solution formulation as noted by **ONE** of the following:
        i. Member utilizes tube feeding (G-tube/J-tube)
        ii. Member has a swallowing disorder or condition affecting ability to swallow
        iii. Member is <13 years of age
    d. If the request is for BRAND NAME Cuvposa® solution, member must meet the above criteria and the prescriber must provide medical records documenting an inadequate response or adverse reaction to the generic glycopyrrolate solution (as per the Brand Name and Non-Preferred Generic Drugs guideline)
2. For members ≥ 17 years of age:
    a. The member has a neurologic condition associated with drooling (e.g. cerebral palsy, Rett syndrome, mental retardation, Parkinson's disease)
    b. Member's current weight to determine appropriate dosing
    c. Medical necessity for use of solution formulation as noted by **ONE** of the following:
        i. Member utilized tube feeding (G-tube/J-tube)
        ii. Member has a swallowing disorder or condition affecting ability to swallow
    d. Physician attestation of an inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
        i. scopolamine patches
        ii. trihexyphenidyl solution
    e. If the request is for BRAND NAME Cuvposa solution, member must meet the above criteria and the prescriber must provide medical records documenting an inadequate response or adverse reaction to the generic glycopyrrolate solution (as per the Brand Name and Non-Preferred Generic Drugs guideline)

Dartisla ODT (glycopyrrolate orally disintegrating tablet)
ALL of the following:

1. Dartisla ODT will be used as an adjunctive therapy in treatment of peptic ulcer*
2. Physician attestation of inadequate response, adverse reaction, or contraindication to glycopyrrolate tablets
3. Medical necessity for use of orally disintegrating formulation as noted by **ONE** of the following:
    a. Member utilizes tube feeding (G-tube/J-tube)
    b. Member has a swallowing disorder or condition affecting ability to swallow
    c. Member is <13 years of age
4. Requested quantity is ≤ 3 units/day

**Requests for a neurologic condition associated with drooling – See appendix*

Glycate (glycopyrrolate 1.5 mg tablet)

1. Medical records documenting clinical rationale why glycopyrrolate 1 mg ang/or 2 mg tablets may not be appropriate

Glycopyrrolate injection

ALL of the following:

1. Glycopyrrolate injection will be used as an adjunctive therapy in treatment of peptic ulcer*
2. Medical necessity for use of injection formulation as noted by **ONE** of the following:
    a. Member utilizes tube feeding (G-tube/J-tube)
    b. Member has a swallowing disorder or condition affecting ability to swallow
    c. Member is <13 years of age

**Requests for a neurologic condition associated with drooling – See appendix*

Continuation of Therapy

Reauthorization requires physician documentation of a positive response to therapy (e.g. less drooling or decreased caregiver burden), documentation of continued necessity of dosage form (which includes updated member weight) and criteria based on age <17 years or ≥17 years.

Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 1 year.
3. The following quantity limits apply:

Dartisla ODT (glycopyrrolate orally disintegrating tablet)	90 tablets per 30 days

Appendix A. Off-label use – Neurologic condition associated with drooling

Glycopyrrolate injection

Prescriber provides documentation of **ALL** of the following:

1. Member's current weight to determine appropriate dosing
2. Medical necessity for use of injection formulation as noted by **ONE** of the following:
    a. Member utilizes tube feeding (G-tube/J-tube)
    b. Member has a swallowing disorder or condition affecting ability to swallow
    c. Member is <13 years of age
3. Physician attestation of an inadequate response, adverse reaction or contraindication to **BOTH** of the following:
    a. glycopyrrolate oral solution
    b. scopolamine patches

Dartisla ODT (glycopyrrolate orally disintegrating tablet)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate dosing (one tablet two or three times daily)
2. Medical necessity for use of orally disintegrating formulation as noted by **ONE** of the following:
    a. Member utilizes tube feeding (J-tube, G-tube)

b. Member has a swallowing disorder or condition affecting ability to swallow
c. Member is < 13 years of age

3. Physician attestation of an inadequate response, adverse reaction or contraindication to **BOTH** of the following:
    a. glycopyrrolate tablets
    b. scopolamine patches

References

1. Cuvposa® [package insert]. Raleigh (NC): Merz Pharmaceuticals; 2021 Mar. 11 Administered for the MassHealth Pharmacy Program
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3. Drugs@FDA [database on the Internet]. Rockville (MD): Food and Drug Administration (US), Center for Drug Evaluation and Research; 2022 [cited 2022 Feb 9]. Available from: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.
4. Micromedex® Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Micromedex; 2022 [cited 2022 Feb 9]. Available from: http://www.thomsonhc.com/.
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Review History
02/08/2023 - Reviewed and created for Feb P&T; Matched MH UPPL criteria. Cuvposa, Dartisla ODT, Glycate, and glycopyrrolate injection were added to pharmacy benefit with a prior authorization. Dartisla ODT will have a quantity limit. Effective 4/1/23.
08/09/23 – Reviewed and updated for P&T. Admin update: benefit change to PB only. Effective 9/1/23