Cuvposa (glycopyrrolate) oral solution
Policy Number: C8453-A

Prior Authorization Criteria

CRITERIA EFFECTIVE DATES:

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<th>ORIGINAL EFFECTIVE DATE</th>
<th>LAST REVIEWED DATE</th>
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<td>8/1/2018</td>
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PRODUCTS AFFECTED:
Cuvposa Sol 1MG/5ML

DRUG CLASS:
Quaternary Anticholinergics

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Retail Pharmacy

AVAILABLE DOSAGE FORMS:
Cuvposa Sol 1MG/5ML

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)

COMPRENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

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

REQUIRED MEDICAL INFORMATION:
A. SEVERE DROOLING:
1. Patient has a diagnosis of a condition associate with severe drooling
AND
2. Trial and failure or intolerance to generic glycopyrrolate tablets.(Adequate trial period of 14 days.)

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of Therapy: for up to 12 months

QUANTITY:
Dosed 0.02 mg/kg/dose orally three times daily. Titrate 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.

PRESCRIBER REQUIREMENTS:
No restriction

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Prior Authorization Criteria

AGE RESTRICTIONS:
3 years and older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. SEVERE DROOLING:
1. Chart notes showing diagnosis
AND
2. Chart notes showing improvement of drooling symptoms while on therapy.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Absolute contraindications include closed-angle glaucoma, gastrointestinal bleeding, gastrointestinal obstruction, hemorrhagic shock, ileus, myasthenia gravis, toxic megacolon, ulcerative colitis, and urinary tract obstruction.

OTHER SPECIAL CONSIDERATIONS: None

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).

APPENDIX: None

REFERENCES:
Last Updated: June 23, 2016. Accessed August 8, 2017