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Clinical Guideline

Guideline Number: PG087, Ver. 3

cromolyn sodium oral concentrate

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Cromolyn sodium is a mast cell stabilizer used to treat conditions such as asthma and allergies. The oral solution formulation is used to treat systemic mastocytosis, a condition in which mast cells (a cell involved in the immune response) accumulates in the organs and causes symptoms such as itching and facial flushing. Medications such as H2 antihistamines (such as cimetidine), proton pump inhibitors (such as omeprazole), and cromolyn can be used to treat systemic mastocytosis.

Definitions

"Mast cell" is a cell found in connective tissue that is involved in immune and allergic responses.

"Mast cell stabilizer" is a class of medications that works by inhibiting the effects of mast cells.

"Systemic mastocytosis" is a condition in which mast cells accumulate in the bone marrow and other organs (such as in the gastrointestinal tract).

Medical Necessity Criteria for Initial Authorization

The Plan considers cromolyn sodium oral concentrate medically necessary when ALL of the following criteria are met:

1. The member has a diagnosis of systemic mastocytosis; ***and***
2. The requested drug is being prescribed to manage gastrointestinal symptoms associated with systemic mastocytosis; ***and***
3. The member has tried and failed therapy with, or has a contraindication to, ONE of the following:
    a. H2 antihistamine (such as cimetidine)
    b. Proton pump inhibitor (such as omeprazole)
4. Chart documentation and supporting labwork are provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, cromolyn sodium oral concentrate will be approved for 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if the member still meets the initial criteria and has chart documentation demonstrating a clinical improvement in symptoms since starting the requested medication:

1. The member's condition has improved or stabilized based upon the prescriber's assessment.

Experimental or Investigational / Not Medically Necessary

Cromolyn sodium oral concentrate for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Cromolyn sodium oral solution, concentrate [package insert]. Woodstock, IL: Catalent Pharma Solutions, LLC; 2009
2. Gotlib J, Gerds AT, Bose P, et al. Systemic Mastocytosis, Version 2.2019, NCCN Clinical Practice Guidelines in Oncology. 2018;16(12):1500-37.

Clinical Guideline Revision / History Information

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