

cromolyn sodium oral concentrate

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member's plan contracts, state laws, and federal laws. Please reference the member's plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

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

Oscar covers cromolyn sodium oral concentrate 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)

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

Medical Necessity Criteria for Reauthorization

All prior authorization renewals will be reviewed on a case-by-case basis to determine if continuation of therapy is medically necessary. Prior Authorization may be extended based on the diagnosis, documentation of the response to therapy, and pharmacy claims record.

Experimental or Investigational / Not Medically Necessary

Cromolyn sodium oral concentrate for any other indication is *not covered* by Oscar, as it is considered 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

Original Date: 11/05/2020 Reviewed/Revised:
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