

## Cromolyn Sodium 100mg/5mL Solution

### 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 medication belonging to a group called mast cell stabilizers. Cromolyn Sodium 100mg/5mL Solution 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 diarrhea, headache, flushing, itching, nausea, vomiting, and stomach pain. Other medications effective for managing symptoms such as abdominal pain, nausea, diarrhea, and bloating in patients with mastocytosis include drugs such as ranitidine, famotidine, or proton pump inhibitors such as omeprazole.

### 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 100mg/5mL Solution** medically necessary when **ALL** of the following criteria are met:

1. The member has a diagnosis of systemic mastocytosis; **AND**
2. The requested medication is being used for symptoms related to **ONE** of the following organ involvement:
  - a. Skin (e.g., pruritus, flushing, urticaria, angioedema dermatographism) **AND** the member is unable to use or has tried and failed:
    - i. H1 blockers (e.g., cetirizine, fexofenadine, loratadine) and H2 blockers (e.g., cimetidine, ranitidine or famotidine); **and**
    - ii. Leukotriene receptor antagonist (e.g., montelukast or zafirlukast); **and**
    - iii. Aspirin; **or**
  - b. Gastrointestinal (e.g., diarrhea, abdominal cramping, nausea, vomiting) **AND** the member is unable to use or has tried and failed:
    - i. H2 blockers (e.g., cimetidine, ranitidine or famotidine); **or**
  - c. Neurologic (e.g., headache, poor concentration and memory, brain fog) **AND** the member is unable to use or has tried and failed:
    - i. H1 blockers (e.g., cetirizine, fexofenadine, loratadine) and H2 blockers (e.g., cimetidine, ranitidine or famotidine); **or**
  - d. Naso-ocular (e.g., nasal stuffiness, nasal pruritus, conjunctival injection) **AND** the member is unable to use or has tried and failed:
    - i. H1 blockers (e.g., cetirizine, fexofenadine, loratadine); **and**
    - ii. Corticosteroids (e.g., hydrocortisone, prednisone, betamethasone, dexamethasone); **AND**
3. Clinical chart documentation is 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 **BOTH** of the following are met:

1. the member still meets the applicable initial criteria; **AND**
2. recent chart documentation (within the last 12 months) shows the member has experienced a clinical benefit (e.g., amelioration of signs and symptoms of the disease including abdominal pain, cognitive dysfunction, diarrhea, flushing, headaches, nausea, pruritus, urticaria, vomiting, and whealing).

### 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) [prescribing information]. Mason, OH: Prasco Laboratories; December 2011.
2. Gastrocrom liquid (cromolyn) [prescribing information]. Somerset, NJ: Meda Pharmaceuticals; April 2015.
3. Gotlib J, Gerds AT, Bose P, et al. Systemic Mastocytosis, Version 2.2019, NCCN Clinical Practice Guidelines in Oncology. 2018;16(12):1500-37.
4. National Comprehensive Cancer Network (NCCN). The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Systemic Mastocytosis. Version 05.2023, 8/8/2023. Accessed September 2023. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/mastocytosis.pdf](https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf).
5. Reiter A., et al.: New developments in diagnosis, prognostication, and treatment of advanced systemic mastocytosis. Blood 2020; 135 (16): pp. 1365-1376.
6. Scherber R.M., et al.: Borate U: How we diagnose and treat systemic mastocytosis in adults. Br J Haematol 2018; 180 (1): pp. 11-23.
7. Sperr W.R., et al.: International prognostic scoring system for mastocytosis (IPSM): a retrospective cohort study. Lancet Haematol 2019; 6 (12): pp. e638-e649.
8. Theohardies T.C., et al.: Mast cells, mastocytosis, and related disorders. N Engl J Med 2015; 373: pp. 163-172.

### Clinical Guideline Revision / History Information

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