Cromolyn Sodium 100mg/5mL Solution

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. Cromolyn is also available as intranasal and ophthalmic dosage forms, this policy does not pertain to those dosage forms. Other medications effective for managing symptoms such as abdominal pain, nausea, diarrhea, and bloating in those with mastocytosis include drugs such as famotidine, or proton pump inhibitors such as omeprazole (Prilosec).

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 (1) 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 ALL of the following:
        i. H1 blocker (e.g., cetirizine, fexofenadine, loratadine) and H2 blockers (e.g., cimetidine 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 ONE (1) of the following:
        i. H2 blocker (e.g., cimetidine or famotidine)*; or*
        ii. Proton pump inhibitors (e.g., omeprazole, esomeprazole, pantoprazole); *or*
    c. Neurologic (e.g., headache, poor concentration and memory, brain fog) AND the member is unable to use or has tried and failed ALL of the following:
        i. H1 blocker (e.g., cetirizine, fexofenadine, loratadine)*; and*
        ii. H2 blocker (e.g., cimetidine 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 ALL of the following:
        i. H1 blocker (e.g., cetirizine, fexofenadine, loratadine)*; and*
        ii. Intranasal corticosteroids (e.g., fluticasone, flunisolide, or triamcinolone) OR systemic corticosteroid (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 up to 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 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 wheeling).

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

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Clinical Guideline Revision / History Information

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