Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

RHAPSIDO® (remibrutinib) PA Criteria FOR Chronic Spontaneous Urticaria:

RHAPSIDO® (remibrutinib) is a Bruton's tyrosine kinase (BTK) inhibitor indicated for chronic spontaneous urticaria (CSU) in adults who remain symptomatic despite H1 antihistamine treatment. NOTE: RHAPSIDO® is not indicated for other forms of urticaria.

Prior authorization is required for RHAPSIDO® (remibrutinib) for CSU. Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 6 Months

1. Age of the patient is within the age range as recommended by the FDA label; **AND**
2. Diagnosis of chronic spontaneous urticaria; **AND**
3. Patient meets ONE of the following scenarios:
    a. Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, two H1 antihistamines (e.g., cetirizine, loratadine, desloratadine, levocetirizine, diphenhydramine); **OR**
    b. Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, BOTH of the following taken in combination:
        i. A second-generation H1 antihistamine (e.g., cetirizine, loratadine, desloratadine, levocetirizine); **AND**
        ii. One of the following:
            1. A different second-generation H1 antihistamine
            2. A first-generation H1 antihistamine (e.g., chlorpheniramine, diphenhydramine, hydroxyzine)
            3. An H2 antihistamine (e.g., famotidine, cimetidine, nizatidine)
            4. A leukotriene modifier (e.g., montelukast); **AND**
4. Prescribed by or in consultation with an allergist, immunologist, or dermatologist; **AND**
5. Patient remains symptomatic despite at least a 2-month trial of, or history of contraindication or intolerance to XOLAIR®; **AND**
6. Patient remains symptomatic despite at least a 2-month trial of, or history of contraindication or intolerance to DUPIXENT®; **AND**

7. Patient does not have mild, moderate, or severe hepatic impairment; **AND**
8. Prescribed dose does not exceed 2 tablets per day.

<u>Re-Authorization</u>: 1 Year

1. Positive clinical response to RHAPSIDO® therapy (e.g., reduction in exacerbation, itching severity, or hives); **AND**
2. Prescribed dose does not exceed 2 tablets per day.

RHAPSIDO® (remibrutinib) Dosing:
- Oral: 25 mg twice daily

Formulation:
- RHAPSIDO® is available as 25 mg tablets.