Pharmacy Medical Necessity Guidelines:
Rhapsido (remibrutinib)

Effective: May 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Rhapsido (remibrutinib) is a kinase inhibitor indicated for the treatment of chronic spontaneous urticaria in adult patients who remain symptomatic despite H1 antihistamine treatment. Rhapsido is not indicated for other forms of urticaria.

COVERAGE GUIDELINES

The plan may authorize coverage of Rhapsido (remibrutinib) for Members when **ALL** of the following criteria are met and limitations do not apply:

Initial Authorization Criteria

1. Documented diagnosis of chronic spontaneous urticaria defined by presence of the condition for at least six (6) weeks

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with an allergist, dermatologist, or immunologist

AND

4. Documentation of **ONE (1)** of the following:
   a. Patient remains symptomatic despite treatment with a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for a minimum of two (2) week trial dosed at a maximum of four times the standard dose
   b. Contraindication to second-generation H1 antihistamines or second-generation H1 antihistamines dosed at a maximum of four times the standard dose

AND

5. Documentation of **ONE (1)** of the following:
   a. Requested medication will be used concurrently with a second-generation H1 antihistamine
   b. Contraindication to second-generation H1 antihistamines

AND

6. Documentation the patient has had an inadequate response to maximum recommended dosing for chronic spontaneous urticaria, adverse reaction, or contraindication to BOTH of the following: Dupixent (dupilumab) and Xolair (omalizumab)

AND

7. Documentation that the requested medication will not be used in combination with another immunotherapy indicated for chronic spontaneous urticaria [e.g., Dupixent (dupilumab), Xolair (omalizumab)]

Reauthorization Criteria

1. Documented diagnosis of chronic spontaneous urticaria defined by presence of the condition for at least six (6) weeks

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with an allergist, dermatologist, or immunologist

AND

4. Documentation of **ONE (1)** of the following:
   a. Requested medication will be used concurrently with a second-generation H1 antihistamine
   b. Contraindication to second-generation H1 antihistamines

AND

5. Documentation the patient has experienced a therapeutic response as defined by **ONE (1)** of the following:
    a. Reduced itching
    b. Reduction in the number and/or size of hives

AND

6. Documentation that the requested medication will not be used in combination with another immunotherapy indicated for chronic spontaneous urticaria [e.g., Dupixent (dupilumab), Xolair (omalizumab)]

LIMITATIONS

1. Rhapsido is limited to 60 tablets per 30 days.
2. Initial request will be approved 6 months. Reauthorization requests will be approved for 12 months.
3. Patients new to the plan stable on Rhapsido should be reviewed against Initial Authorization Criteria.

CODES

None

REFERENCES

1. Giménez-Arnau A, Szalewski R, Hide M, et al.Remibrutinib in chronic spontaneous urticaria: 52-week results from two phase 3 studies. *J Allergy Clin Immunol*. 2026 Jan;157(1):143-154.
2. Rhapsido (remibrutinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2025.
3. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2022 Mar. 77 (3):734-766.

APPROVAL HISTORY

April 14, 2026: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.