Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Rhapsido (remibrutinib)

Effective: June 1, 2026

Guideline Type	☒ Prior Authorization ☒ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

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

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Rhapsido (remibrutinib) for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of chronic spontaneous urticaria

AND

2. Documentation of persistent symptoms of chronic spontaneous urticaria for at least six (6) weeks despite use of a second generation H1 antihistamine, unless contraindicated

AND

3. Patient is 18 years of age or older

AND

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

AND

5. Documentation of history of failure to a minimum two (2) week trial with a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) dosed to a maximum of four times the approved dose, unless contraindicated *(Note: document drug, date and duration of trial)*

AND

6. Documentation the requested medication will be used concurrently with a second-generation H1 antihistamine, unless contraindicated

AND

7. Documentation of history of failure to two (2) of the listed medications from each of the following therapeutic categories (only one medication is required if only one is available for a listed therapeutic category), unless contraindicated *(Note: document drugs, dates, and duration of trials):*
    a. Interleukin Antagonists: Dupixent (dupilumab)
    b. Anti-IgE antibody: Xolair (omalizumab) dosed at least 300mg every 4 weeks

AND

8. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-4 therapy (e.g., dupilumab)
    b. Anti-IgE therapy (e.g., omalizumab)

Reauthorization Criteria

1. Documented diagnosis of chronic spontaneous urticaria

AND

2. Patient is 18 years of age or older

AND

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

AND

4. Submission of medical charts documenting the patient has experienced a therapeutic response to therapy as defined by **one (1)** of the following:
    a. Reduced itching
    b. Reduction in the number and/or size of hives

AND

9. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-4 therapy (e.g., dupilumab)
    b. Anti-IgE therapy (e.g., omalizumab)

Limitations

1. Initial approval will be authorized for six (6) months. Reauthorization will be provided in 12-month intervals.
2. Members new to the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.
3. Members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against Initial Authorization Criteria.

References

1. Rhapsido (remibrutinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2025.
2. 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; 77:734.

Approval And Revision History

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

Subsequent endorsement date(s) and changes made:

- May 12, 2026: Removed “Documentation the requested medication will be used concurrently with a second generation H1 antihistamine, unless contraindicated” from Reauthorization Criteria (eff 6/1/26).

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.