VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Bruton's Tyrosine Kinase Inhibitor – Rhapsido Prior Authorization Policy
- Rhapsido® (remibrutinib tablets – Novartis)

REVIEW DATE: 10/01/2025; selected revision 10/29/2025

OVERVIEW

Rhapsido, a Bruton's kinase (BTK) inhibitor, is indicated for **chronic spontaneous urticaria** (CSU) in adults who remain symptomatic despite H_1 antihistamine treatment.[1] Limitation of use: Rhapsido is not indicated for other forms of urticaria.

Clinical Efficacy

Chronic Spontaneous Urticaria

The pivotal studies of Rhapsido in patients with chronic spontaneous urticaria involved patients who were symptomatic despite treatment with a second-generation H_1 antihistamine.[1,2] Continued symptomatic disease was defined as itch and hives for ≥ 6 consecutive weeks prior to screening. During the randomized treatment period, patients continued to receive background therapy with a stable dose of a second-generation H_1 antihistamine. Rescue treatment with another second-generation H_1 antihistamine was allowed at ≤ 4 times the standard dose. The primary efficacy endpoints were evaluated following 12 weeks of treatment; efficacy was sustained at Week 24.

Guidelines

Chronic Spontaneous Urticaria Guidelines

Guidelines for the definition, classification, diagnosis, and management of urticaria have been published by the European Academy of Allergy and Clinical Immunology/Global Allergy and Asthma European Network/European Dermatology Forum/Asia Pacific Association of Allergy, Asthma and Clinical Immunology (2022).[2] The American Academy of Dermatology was involved in the development of these guidelines and endorses their recommendations. Chronic spontaneous urticaria is defined as the appearance of wheals, angioedema, or both for > 6 weeks due to known or unknown causes. Signs and symptoms may be present daily/almost daily or have an intermittent recurrent course. Second-generation H_1 antihistamines taken regularly are the recommended first-line treatment for all types of urticaria following elimination of possible underlying causes. If standard doses do not eliminate urticaria signs and symptoms, the dose of the antihistamine should be increased up to 4-fold. Guidelines have not been updated since the approval of Rhapsido.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rhapsido. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Rhapsido as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Rhapsido to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rhapsido is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Chronic Spontaneous Urticaria.** Approve Rhapsido for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has/had urticaria for ≥ 6 weeks (prior to treatment with Rhapsido); AND
     - **iii.** According to the prescriber, the patient has tried high-dose oral second-generation H_1 antihistamine therapy; AND
       Note: High-dose oral second-generation H_1 antihistamine therapy is the highest dose tolerated by the patient and can be up to four times the FDA-approved dose. Examples of second-generation H_1 antihistamines are cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine.
     - **iv.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist; OR
   - **B)** Patient is Currently Receiving Rhapsido. Approve Rhapsido for 1 year if the patient meets BOTH the following criteria (i and ii):
     - **i.** Patient has already received at least 6 months of therapy with Rhapsido; AND
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with Rhapsido should be considered under criterion 1A (Chronic Spontaneous Urticaria, Initial Therapy).
     - **ii.** Patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, or c):
       - **a)** Decreased itch severity; OR
       - **b)** Decreased number of hives; OR
       - **c)** Decreased size of hives

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rhapsido is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Rhapsido® tablets [prescribing information]. East Hanover, NJ: Novartis; 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;73:734-766.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/01/2025
Selected Revision	**Chronic Spontaneous Urticaria:** The initial approval duration was changed from 3 months to 6 months. Criteria were clarified to require that the patient has/had urticaria for ≥ 6 weeks (previously required > 6 weeks). The requirement that the patient have urticaria symptoms that have been present for > 3 days per week despite daily non-sedating H_1 antihistamine therapy with doses that have been titrated up to a maximum of four times the standard FDA-approved dose was removed. This was replaced with a requirement that the patient has tried high-dose oral second-generation H_1 antihistamine therapy, according to the prescriber. A "Note" was added to clarify that high-dose oral second-generation H_1 antihistamine therapy is the highest dose tolerated by the patient and can be up to four times the FDA-approved dose. Criteria for a patient currently receiving Rhapsido were updated to apply to a patient who has already received at least 6 months of therapy with Rhapsido; previously, these criteria applied to a patient who had already received at least 3 months of therapy with Rhapsido. The "Note" was updated to reflect that a patient who has received < 6 months of therapy should be considered under Chronic Spontaneous Urticaria, Initial Therapy. Previously, this "Note" referred a patient who has received < 3 months of therapy to Initial Therapy criteria.	10/29/2025