Drug Coverage Policy

Effective Date.....1/15/2026
Coverage Policy Number.....IP0771
Policy Title.....Rhapsido

Bruton's Tyrosine Kinase Inhibitor – Rhapsido

- Rhapsido® (remibrutinib tablets – Novartis)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for 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.

Rhapsido is/are considered medically necessary when the following are met:

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 Covered

Rhapsido for any other use is considered not medically necessary. 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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	1/15/2026

The policy effective date is in force until updated or retired.