

DRUG POLICY

Rhapsido™ (remibrutinib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Rhapsido is indicated for the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use

Rhapsido is not indicated for other forms of urticaria.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. For initial requests:
 - a. Chart notes or medical records and claims history of prior treatments documenting dosage, duration, and response to therapy.
2. For continuation requests:
 - a. Chart notes or medical records and documenting a positive clinical response to therapy (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]).

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Allergist
2. Immunologist

3. Dermatologist

Criteria for Initial Approval

Chronic Spontaneous Urticaria (CSU)

Authorization of 6 months may be granted when the requested drug is being prescribed for the treatment of chronic spontaneous urticaria (CSU) in adult members when ALL of the following criteria are met:

1. The requested drug will NOT be used in combination with any other biologic or targeted synthetic drug for the same indication.
2. The member has experienced a spontaneous onset of wheals (hives), angioedema, or both for at least 6 weeks.
3. The member has been evaluated for other causes of wheals (hives) and/or angioedema, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis).
4. The member remains symptomatic despite treatment with up-dosing [in accordance with the international guidelines for urticaria (EAACI/GA2LEN/EuroGuiDerm/APAAACI)] of a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.

Continuation of Therapy

Chronic Spontaneous Urticaria (CSU)

Authorization of 12 months may be granted when the requested drug is being prescribed for the treatment of chronic spontaneous urticaria (CSU) in adult members when ALL of the following criteria are met:

1. The requested drug will NOT be used in combination with any other biologic or targeted synthetic drug for the same indication.
2. The member has experienced a positive clinical response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy.

Other

Rhapsido (remibrutinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Rhapsido (remibrutinib) 25 mg tablet	60 tablets per 30 days	25 mg twice daily

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

Rhapsido [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.; September 2025.

Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; June 2025.

Xolair [package insert]. South San Francisco, CA: Genetech, Inc.; February 2024.

Lexicomp Online, Lexi-Drugs Online. Hudson, OH: UpToDate, Inc.; 2025; Accessed October 20, 2025.

Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/20/2025).

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.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.06.23

Original Effective Date: March 13, 2026

Reviewed:

Revised:

Current Effective Date: March 13, 2026