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Section:	Prescription Drugs	**Effective Date:**	September 11, 2026
Subsection:	Miscellaneous Products	**Original Policy Date:**	January 1, 2026
Subject:	Rhapsido	**Page:**	1 of 5

Last Review Date: March 6, 2026

Rhapsido

Description

Rhapsido (remibrutinib)

Background
Rhapsido (remibrutinib) is an oral, small molecule kinase inhibitor that inhibits Bruton's tyrosine kinase (BTK). BTK is an intracellular protein expressed in mast cells, basophils, B cells, macrophages, and thrombocytes. BTK is involved in intracellular signaling. Rhapsido also inhibits the BTK-related kinases tec protein tyrosine kinase (TEC) and BMX non-receptor tyrosine kinase (BMX). Rhapsido inhibits mast cell and basophil degranulation, including release of histamine and other proinflammatory mediators, mediated by pathogenic IgE or IgG (1).

Regulatory Status
FDA-approved indication: Rhapsido is a kinase inhibitor indicated for the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite H1 antihistamine treatment (1).

Limitations of Use: (1)
- Not indicated for other forms of urticaria.

Rhapsido has warnings for risk of bleeding and live attenuated vaccines. Treatment with Rhapsido should be interrupted for 3 to 7 days pre- and post-surgery or invasive procedures. Use of antithrombotic agents concomitantly with Rhapsido may further increase the risk of bleeding. Monitor for signs and symptoms of bleeding. The use of live and live-attenuated vaccines should be avoided in patients receiving Rhapsido (1).

The safety and effectiveness of Rhapsido in pediatric patients less than 18 years of age have

not been established (1).

Related policies
Dupixent, Xolair

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rhapsido may be considered **medically necessary** if the conditions indicated below are met.

Rhapsido may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic spontaneous urticaria (CSU)

AND ALL of the following:

1. Symptomatic after at least **TWO** previous trials of H1-antihistamines
2. Baseline urticaria activity score (UAS)
   (e.g., *https://www.mdcalc.com/urticaria-activity-score-uas*)
3. **NO** dual therapy with another monoclonal antibody for the treatment of CSU (see Appendix 1)
4. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic spontaneous urticaria (CSU)

AND ALL of the following:

1. Decrease in urticaria activity score (UAS), such as improvement in pruritic wheals, hives, and itching
   (e.g., *https://www.mdcalc.com/urticaria-activity-score-uas*)
2. **NO** dual therapy with another Prior Authorization (PA) medication for the treatment of CSU (see Appendix 1)
3. **NOT** given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 50 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Rhapsido is a kinase inhibitor indicated for the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite H1 antihistamine treatment. The safety and effectiveness of Rhapsido in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Rhapsido while maintaining optimal therapeutic outcomes.

References

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

Policy History

Date	Action
January 2026	Addition to PA
March 2026	Annual review
September 2026	Per FEP, removed documentation and trial and failure requirements

Keywords

This policy was effective with interim approval on September 11, 2026 and will be reviewed by the FEP® Pharmacy and Medical Policy Committee on December 11,2026.

Appendix 1 - List of PA Medications for CSU

Generic Name	Brand Name
dupilumab	Dupixent
omalizumab	Xolair
remibrutinib	Rhapsido