Effective Date: 5/1/2026
Reviewed: 2/26 Scope: Medicaid

RHAPSIDO (remibrutinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendia uses are considered a covered benefit 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.

Limitation of use: Rhapsido is not indicated for other forms of urticaria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 3 months may be granted for treatment of CSU when ALL of the following criteria are met:

1. Member is 18 years of age or older
2. The requested drug is being prescribed by or in consultation with an allergist, immunologist or dermatologist.
3. Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis), and is not considered to have any other form(s) of urticaria
4. Member's baseline documentation score from an objective clinical evaluation tool, such as urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), urticaria control test (UCT), angioedema control test (AECT), or Chronic Urticaria Quality of Life Questionnaire (CU-QoL), is provided
5. Documentation that the member has experienced a spontaneous onset of wheals (hives), angioedema, or both for at least 6 weeks
6. Documentation that the member remains symptomatic despite treatment with up-dosing to fourfold (in accordance with EAACI/GA2LEN/EuroGuiDerm/APAAACI guidelines) of second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.
7. Documentation that the member has had an inadequate response to Xolair (at least 300 mg every 4 weeks) for the treatment of CSU or member has an intolerance or contraindication to Xolair
8. Member does not have mild, moderate or severe hepatic impairment (Child-Pugh Class A, B, and C)
9. The requested drug will NOT be used in combination with any other biologic or targeted synthetic drug for the same indication (e.g., Dupixent, Xolair).

III. CONTINUATION OF THERAPY

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

1. The requested drug is being prescribed by or in consultation with an allergist, immunologist or dermatologist.
2. Documentation that the member has experienced clinical improvement since initiation of Rhapsido therapy as documented by improvement from baseline using an objective clinical evaluation tool, such as: urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-QoL).
3. The requested drug will NOT be used in combination with any other biologic or targeted synthetic drug for the same indication (e.g., Dupixent, Xolair).

IV. QUANTITY LIMIT

Rhapsido 25 mg tablets: 60 tablets per 30 days

V. REFERENCES

1. Rhapsido [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.; September 2025.
2. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; June 2025.
3. Xolair [package insert]. South San Francisco, CA: Genetech, Inc.; February 2024.
4. Lexicomp Online, Lexi-Drugs Online. Hudson, OH: UpToDate, Inc.; 2025; Accessed October 20, 2025.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 10/20/2025).
6. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022 Mar;77(3):734-766.