Reference number(s)
7242-C

Initial Prior Authorization with Quantity Limit Rhapsido

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rhapsido	remibrutinib

Indications

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.

Coverage Criteria

Authorization 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:

- The requested drug is being prescribed by or in consultation with an allergist, immunologist or dermatologist.

- The requested drug will NOT be used in combination with any other biologic or targeted synthetic drug for the same indication.
- The patient has previously received a biologic drug (e.g., Xolair, Dupixent) indicated for CSU in the past year. [ACTION REQUIRED: Documentation is required for approval.]
- If the patient has NOT received a biologic drug (e.g., Xolair, Dupixent) indicated for CSU in the past year, then ALL of the following criteria are met:
    - The patient has experienced a spontaneous onset of wheals (hives), angioedema, or both for at least 6 weeks.
    - The patient 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).
    - The patient remains symptomatic despite treatment with up-dosing (in accordance with EAACI/GA2LEN/EuroGuiDerm/APAAACI guidelines) of a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks. [ACTION REQUIRED: Documentation is required for approval.]

Continuation of Therapy

Authorization 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:

- The requested drug is being prescribed by or in consultation with an allergist, immunologist or dermatologist.
- The requested drug will NOT be used in combination with any other biologic or targeted synthetic drug for the same indication.
- The patient has experienced a positive clinical response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy. [ACTION REQUIRED: Documentation is required for approval.]

Quantity Limits Apply

60 tablets / 25 days or 180 tablets / 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 7242-C: Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months

Reference number(s)
7242-C

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/GA^{2}LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022 Mar;77(3):734-766.