

ALASKA MEDICAID
Prior Authorization Criteria

**Rhapsido®
(remibrutinib)**

FDA INDICATIONS AND USAGE¹

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

APPROVAL CRITERIA^{1,2,3}

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a dermatologist, allergist or immunologist **AND**;
3. Patient has the diagnosis of chronic spontaneous urticaria **AND**;
4. Patient has had urticaria for at least 6 weeks with symptoms present on 3 or more days a week while taking a non-sedating H1 antihistamine titrated to maximum dose **AND**;
5. Patient has been evaluated for medications known to cause or worsen urticaria (e.g. NSAIDs) and these agents have been reduced or discontinued where feasible **AND**;
6. Patient has tried and failed or has a documented clinical contraindication to a non-sedating H1 antihistamine at maximum dose for a minimum of 60 days

DENIAL CRITERIA¹

1. Failure to meet approval criteria **OR**;
2. Being used in conjunction with another biologic medication (e.g. Dupixent, Xolair, etc.)

CAUTIONS¹

- Rhapsido® has been associated with an increased risk of mucocutaneous-related bleeding. Concomitant use with antithrombotic agents may further increase this risk.
- Concomitant use with strong CYP3A4 inhibitors or inducers should be avoided
- The most common adverse reactions include nasopharyngitis, bleeding, headache, nausea, and abdominal pain.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to one year

QUANTITY LIMIT

- 60 tablets per 30 days

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REFERENCES / FOOTNOTES:

1. Rhapsido®(remibrutinib) [prescribing information]. East Hanover, NJ: Novartis; September 2025
2. The International EAACI/GA2 LEN/EuroGuiDerm/APAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022 Mar;77(3):734-766
3. Metz M, Gimenez-Arnau A, Hide M, et al. Remibrutinib in chronic spontaneous urticaria. N Engl J Med. 2025;392(10):984-994.