Last review: 4.2026

Rhapsido (remibrutinib)- ARBCBS Custom Criteria

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

DOCUMENTATION

Chronic Spontaneous Urticaria (CSU)

a. Initial requests:
   i. Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy
b. Continuation requests:
   i. Chart notes or medical record documentation supporting positive response to therapy

PRESCRIBER SPECIALTIES

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

- Chronic spontaneous urticaria: allergist/immunologist or dermatologist

CHRONIC SPONTANEOUS URTICARIA

INITIAL APPROVAL STANDARD REVIEW for up to 6 months:

1. Individual is 18 years of age or older ; **AND**
2. Other etiologies of urticaria have been excluded and there is no diagnosis of a more specific etiology (e.g., allergic, contact, vibratory, thermal or cholinergic urticaria); **AND**
3. Individual has the presence of recurrent urticaria, angioedema or both for a period of at least 6 weeks (Saini, 2021); **AND**
4. There must be a clear documentation of physical findings characteristic of CSU (see policy guidelines (Zuberbier, 2018); **AND**
5. Individual is not being treated concurrently with another biologic agent for the same or similar condition (such as omalizumab, dupilumab, benralizumab, mepolizumab, reslizumab or tezepelumab); **AND**
6. Individual has had an inadequate response to at least four weeks of treatment with up-dosing of a second-generation H-1 antihistamine (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) used in combination with an H2-antihistamine (e.g., cimetidine, famotidine) and a leukotriene modifier (e.g.,

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montelukast, zafirlukast) (Bernstein, 2014); **AND**
7. Must be dosed in accordance with the FDA label.

CONTINUED APPROVAL for up to 12 months:
For **ALL** individuals:

1. Must be dosed in accordance with the FDA label; **AND**
2. Individual is not being treated concurrently with another biologic agent for the same or similar condition (such as omalizumab, dupilumab, benralizumab, mepolizumab, reslizumab or tezepelumab).
3. Individual is 18 years of age or older **AND**
4. Individual has experienced a positive clinical response compared to baseline (e.g.,reduction in exacerbations, itch severity, hives, decrease in weekly urticaria activity score [UAS7] since initiation of therapy)
5. Medication is ordered by or in consultation with a dermatologist or allergist/immunologist

Clinical skin manifestations of CSU (Zuberbier, 2018):

1. An area of central swelling of various size and shape, usually with surrounding erythema, although erythema may be difficult to appreciate on darker skin tones.
2. An itching sensation.
3. A fleeting time course for an individual lesion (usually 30 minutes to 24 hours) with the skin returning to normal without ecchymoses (while skin returns to normal, new lesions may be developing spontaneously at other sites).

Angioedema, if present, in urticaria patients is characterized by (Zuberbier, 2018):

1. A sudden, pronounced erythematous or skin colored swelling of the lower dermis and subcutis or mucous membranes.
2. Sometimes pain, rather than itch.
3. A resolution slower than that of wheals (can take up to 72 hours).

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References

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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/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022 Mar;77(3):734-766.
7. 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.
8. Bernstein DI, Blessing-Moore J, Cox L, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. American Academy of Allergy, Asthma & Immunology Practice Parameter. http://www.aaaai.org/practice-resources/statements-and-practice-parameters/practice-parameter-guidelines.aspx. Accessed March 1, 2025.

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