Reference number(s)
7565-C

This document applies to the following:

Formulary	Applies
Advanced Control (ACF)	☑
Advanced Control Formulary Chart (ACFC)	☐
Advanced Control – Choice (ACCF)	☐
Basic Control (BC)	☐
Basic Control Chart (BCC)	☐
Standard Control (SF)	☑
Standard Control Formulary Chart (SFC)	☐
Standard Control – Choice (SCCF)	☐
Value (VF)	☐
Value Formulary Chart (VFC)	☐

Formulary	Applies
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Aetna Fully Insured Advanced Control Formulary (Aetna FI ACF)	☐
Aetna Fully Insured Advanced Control Formulary Chart (Aetna FI ACFC)	☐
Aetna Fully Insured Standard Opt-Out (Aetna FI SOO)	☐

Exception Criteria
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.

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Coverage Criteria

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

- The patient CANNOT be treated with a formulary alternative (Available Formulary Alternatives: Xolair, Dupixent).
- The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Xolair AND Dupixent. [ACTION REQUIRED: Documentation is required for approval.]
- The patient is 18 years of age or older.
- 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 spontaneous onset of wheals (hives), angioedema, or both for at least 6 consecutive 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.]

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)

- 7565-C: DOA: 12 months

References

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

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2. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; April 2026.
3. Xolair [package insert]. South San Francisco, CA: Genetech, Inc.; February 2024.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2026. https://online.lexi.com. Accessed August 6, 2026.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 08/06/2026).
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;77(3):734-766.
7. Metz M, Giménez-Arnau A, Hide M, et al. Remibrutinib in Chronic Spontaneous Urticaria. N Engl J Med. 2025;392(10):984-994.

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