UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2392-1
Program	Prior Authorization/Medical Necessity
Medications	Rhapsido® (remibrutinib)
P&T Approval Date	2/2026
Effective Date	5/1/2026

1. Background:

Rhapsido is a kinase inhibitor 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.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Rhapsido** will be approved based on **all** of the following criteria:

   a. Diagnosis of chronic spontaneous urticaria

   -AND-

   b. **One** of the following:

      (1) Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, **two** H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]^

      -OR-

      (2) Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to **both** of the following taken in combination^:

         (a) A second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

         -AND-

         (b) **One** of the following:

            i. A different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]
            ii. A first generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]

iii. An H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]
iv. A leukotriene modifier [e.g., Singulair (montelukast)]

-AND-

c. Patient is not receiving Rhapsido in combination with Dupixent (dupilumab) or Xolair (omalizumab) for treatment of the same indication.

-AND-

d. Prescribed by **one** of the following:

(1) Allergist
(2) Dermatologist
(3) Immunologist

Authorization will be issued for 12 months.

B. Reauthorization

1. **Rhapsido** will be approved based on **all** of the following criteria:

a. Documentation of positive clinical response to Rhapsido therapy (e.g., reduction in exacerbations, itch severity, hives)

-AND-

b. Patient is not receiving Rhapsido in combination with Dupixent (dupilumab) or Xolair (omalizumab) for treatment of the same indication.

-AND-

c. Prescribed by **one** of the following:

(1) Allergist
(2) Dermatologist
(3) Immunologist

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
^Tried/failed alternative(s) are supported by FDA labeling.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limitations may be in place

4. References:

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

Program	Prior Authorization/Medical Necessity - Rhapsido (remibrutinib)
Change Control	
2/2026	New program.