Applicable Drugs: Wayrilz (rilzabrutinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 10/23/2025

Date Last Reviewed / Revised: 10/23/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to VIII are met)

I. Documented diagnosis of persistent or chronic immune thrombocytopenia (ITP).

II. Documented platelet count < 30 x 10^9 in the absence of anemia, leukopenia, or other identifiable causes of thrombocytopenia (eg, medications).

III. Documented insufficient response to BOTH of the following:

   A. Corticosteroids (eg, prednisone or dexamethasone).

   B. Immunoglobulins (eg, IVIG or anti-D).

IV. Documented trial or contraindication to ONE of the following:

   A. Eltrombopag

   B. Romiplostim

   C. Rituximab

   D. Fostamatinib

V. Minimum age requirement: 18 years old.

VI. Treatment must be prescribed by or in consultation with a hematologist.

VII. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VIII. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Absolute neutrophil count < 1.5x10^9 / L
- AST/ALT > 1.5 times the upper limit of normal
- Total bilirubin > 1.5 times the upper limit of normal
- eGFR < 50mL/min/1.73 m^2 (Cockcroft and Gault method)

- Active infection
- Myelodysplastic Syndrome

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 800 mg dose/day: Sixty 400mg tablets per 30 days.

APPROVAL LENGTH

- **Authorization:** 3 months.
- **Re-Authorization Length and Renewal Criteria:** 12 months, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective **AND** must meet the following criteria:
    1. Documented improvement in platelet count (> 50 x 10^9 / L).
    2. Adherence to treatment regimen.

APPENDIX

N/A

REFERENCES

1. Wayrilz. Prescribing Information. Sanofi; 2025. Accessed October 20, 2025. https://products.sanofi.us/wayrilz/wayrilz.pdf
2. Kuter DJ, Bussel JB, Ghanima W, et al. Rilzabrutinib *versus* placebo in adults and adolescents with persistent or chronic immune thrombocytopenia: LUNA 3 phase III study. Ther Adv *Hematol*. 2023;14:20406207231205431. Published 2023 Oct 18. doi:10.1177/20406207231205431
3. Kuter DJ, Bussel JB, Ghanima W, et al. Safety and efficacy of rilzabrutinib vs placebo in adults with immune thrombocytopenia: the phase 3 LUNA3 study. Blood. 2025; 145 (24): 2914–2926. doi: https://doi.org/10.1182/blood.2024027336
4. Haymarket Medical Network. Immune Thrombocytopenia (ITP). Rare Disease Advisor. n.d. Updated October 10, 2022. Accessed October 20, 2025. https://www.rarediseaseadvisor.com/disease-info-pages/immune-thrombocytopenia-overview/
5. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv. 2019;3(23):3829–3866. doi:10.1182/bloodadvances.2019000966

6. IPD Analytics. RxInsights New Drug Review: Wayrilz® (rilzabrutinib*)*. September 2025. Accessed October 20, 2025. https://secure.ipdanalytics.com/User/Handler/ViewReport.ashx?type=RP&file=s3%3a%2f%2fipdanalytics%2fReports%2fIPD+Analytics_RxInsights_New+Drug+Review_Wayrilz__09+2025.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.