

PHARMACY POLICY STATEMENT

Nevada Medicaid

DRUG NAME	Wayrilz (rilzabrutinib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Wayrilz is a Bruton’s tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. It mediates its therapeutic effect through immune modulation.

ITP is a rare autoimmune disorder characterized by low levels of platelets due to platelet destruction and insufficient platelet production. ITP duration of less than 3 months is referred to as newly diagnosed, 3-12 months as persistent, and greater than 12 months is considered chronic.

Wayrilz showed a durable platelet response compared to placebo in the phase 3 LUNA 3 clinical trial. It also reduced need of rescue medication and improved bleeding scores and physical fatigue.

Wayrilz (rilzabrutinib) will be considered for coverage when the following criteria are met:

Immune Thrombocytopenia (ITP)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has a documented diagnosis of persistent or chronic ITP of at least 3 months duration; AND
4. Member has had an insufficient response with at least one of the following treatments:
 - a) Corticosteroid
 - b) Immunoglobulin
 - c) Splenectomy; AND
5. Member meets one of the following:
 - a) Current platelet count is $< 30 \times 10^9/L$
 - b) $30 \times 10^9/L$ to $< 50 \times 10^9/L$ with one of the following:
 - i) Active symptomatic bleeding other than minor mucocutaneous bleeding
 - ii) High risk factor for bleeding (i.e., on an anticoagulant, of older age (>60 years), other clearly identified comorbidity); AND
6. Member has tried and failed at least 2 established 2nd line drugs for ITP (e.g., TPO-RA, Tavalisse); AND
7. Member does NOT have secondary immune thrombocytopenia (i.e., non-idiopathic, due to another condition).
8. **Dosage allowed/Quantity limit:** 400 mg orally twice daily. QL: 60 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes include documentation of achieving and maintaining a platelet count of at least $50 \times 10^9/L$; AND
2. Decreased need for rescue medication.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Wayrilz (rilzabrutinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/12/2025	New policy for Wayrilz created.

References:

1. Wayrilz [prescribing information]. Genzyme Corporation; 2025.
2. Kuter DJ, Ghanima W, Cooper N, 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:10.1182/blood.2024027336
3. Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv*. 2019;3(22):3780-3817. doi:10.1182/bloodadvances.2019000812
4. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia [published correction appears in *Blood Adv*. 2020 Jan 28;4(2):252]. *Blood Adv*. 2019;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966
5. Neunert CE, Arnold DM, Grace RF, Kuhne T, McCrae KR, Terrell DR. The 2022 review of the 2019 American Society of Hematology guidelines on immune thrombocytopenia. *Blood Adv*. 2024;8(13):3578-3582. doi:10.1182/bloodadvances.2023012541

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Revised date: 09/12/2025