

Drug Policy

Policy:	Wayrilz® (remibrutinib tablets – Novartis)	Annual Review Date: 07/16/2026 Last Revised Date: 07/16/2026
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OVERVIEW

Wayrilz, a Bruton's tyrosine kinase inhibitor, is indicated for **persistent or chronic immune thrombocytopenia (ITP)** in adults who have had an insufficient response to a previous treatment.¹

The safety and efficacy of Wayrilz have not been established in pediatric patients.

POLICY STATEMENT

This policy involves the use of Wayrilz. Prior authorization is recommended for pharmacy benefit coverage of Wayrilz. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Wayrilz as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Wayrilz be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Wayrilz is recommended in those who meet the following criteria:

- 1. Immune Thrombocytopenia, Chronic or Persistent.** Approve if the patient meets ONE of the following (A or B):
 - A) Initial Therapy.** Approve for 3 months if the patient meets ALL of the following (i, ii, iii, and iv):
 - i.** Patient is ≥ 18 years of age; AND
 - ii.** Patient meets ONE of the following* (a or b):
 - a)** Patient has a platelet count $< 30 \times 10^9/L$ ($< 30,000/mcL$); OR
 - b)** Patient meets BOTH of the following [(1) and (2)]:
 - (1)** Patient has a platelet count $< 50 \times 10^9/L$ ($< 50,000/mcL$); AND
 - (2)** According to the prescriber, the patient is at an increased risk of bleeding; AND
 - iii.** Patient meets ONE of the following* (a or b):
 - a)** Patient has tried at least ONE other therapy; OR

Drug Policy

Note: Examples of therapies are systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, eltrombopag olamine tablets and oral suspension, Alvaiz (eltrombopag choline tablets), Nplate (romiplostim subcutaneous injection), Doptelet (avatrombopag tablets), Tavalisse (fosfatanib tablets), or rituximab.

- b) Patient has undergone splenectomy; AND
- iv. The medication is prescribed by or in consultation with a hematologist; OR
- B) Patient is Currently Receiving Wayrilz. Approve for 1 year if the patient meets BOTH of the following (i and ii):
 - i. According to the prescriber, the patient demonstrates a beneficial clinical response*; AND
Note: A beneficial response can include increased platelet counts, maintenance of platelet counts, and/or a decreased frequency of bleeding episodes; AND
 - ii. Patient remains at risk for bleeding complications.

Initial Approval/ Extended Approval.

A) *Initial Approval:* 3 months

B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Wayrilz has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

*Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Wayrilz™ tablets [prescribing information]. Cambridge, MA: Genzyme/Sanofi; August 2025.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv.* 2019;3(23):3829-3866.

Drug Policy

3. Neunert CE, Arnold DM, Grace RF, et al. The 2022 review of the 2019 American Society of Hematology guidelines on immune thrombocytopenia. *Blood Adv.* 2024;8(13):3578-2582.