

DRUG POLICY

Wayrilz® (rilzabrutinib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Treatment of adult patients with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. For initial requests: Untransfused platelet count
2. For continuation requests: Current platelet count

Exclusions

Coverage will not be provided for members with the following exclusion:

- Concomitant use of the requested drug with other thrombopoietin receptor agonists (e.g., Alvaiz, Promacta, Nplate, Doptelet, Mulpleta), or with spleen tyrosine kinase inhibitors (e.g., Tavalisse).

Preferred Drug Plan Design

Member must meet BOTH the Preferred Drug Plan Design and the Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Criteria for initial approval for Wayrilz will only apply when one of the following criteria are met:

1. Member has had an inadequate response to treatment or intolerable adverse event with Alvaiz (eltrombopag choline) or eltrombopag olamine (generic Promacta)..
2. Member has a clinical reason to avoid Alvaiz (eltrombopag choline) and eltrombopag olamine (generic Promacta).
3. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome.

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. This medication must be prescribed by or in consultation with a hematologist or oncologist.

Criteria for Initial Approval

Chronic immune thrombocytopenia (ITP)

1. Authorization of 6 months may be granted to adult members with chronic ITP who meet ALL of the following criteria:
 - A. Member has an inadequate response or intolerance to prior therapy such as corticosteroids, immunoglobulins, splenectomy, or thrombopoietin receptor agonists.
 - B. Member has an untransfused platelet count at any point prior to the initiation of the requested medication that is less than $30 \times 10^9/L$ OR $30 \times 10^9/L$ to $50 \times 10^9/L$ with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma) OR risk factors for bleeding (see Appendix).

Continuation of Therapy

Chronic immune thrombocytopenia (ITP)

1. Authorization of 3 months may be granted to members with current platelet count less than $50 \times 10^9/L$ for whom the platelet count is not sufficient to prevent clinically important bleeding and who have not received a maximal dose of the requested drug for at least 4 weeks.
2. Authorization of 12 months may be granted to members with current platelet count less than $50 \times 10^9/L$ for whom the current platelet count is sufficient to prevent clinically important bleeding.
3. Authorization of 12 months may be granted to members with current platelet count of $50 \times 10^9/L$ to $200 \times 10^9/L$.
4. Authorization of 12 months may be granted to members with current platelet count greater than $200 \times 10^9/L$ to less than or equal to $400 \times 10^9/L$ for whom dosing for the requested drug will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

Other

Wayrilz (rilzabrutinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Wayrilz (rilzabrutinib) 400 mg oral tablet	60 tablets per 30 days	400 mg orally twice daily

Appendix

Examples of risk factors for bleeding (not all inclusive)

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidity (e.g., peptic ulcer disease, hypertension)
- Mandated anticoagulation therapy
- Profession (e.g., construction worker) or lifestyle (e.g., plays contact sports) that predisposes patient to trauma

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Wayrilz [package insert]. Cambridge, MA: Genzyme Corporation; August 2025.
- The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed October 10, 2025.
- 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.
- Rodeghiero F, Stasi R, Gernsheimer T, et al. Standardization of terminology, definitions and outcome criteria in immune thrombocytopenic purpura of adults and children: report from an international working group. *Blood*. 2009;113(11):2386-2393.

POLICY HISTORY

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