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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Hematological Agents	**Original Policy Date:**	October 3, 2025
Subject:	Wayrilz	**Page:**	1 of 4

Last Review Date: December 12, 2025

Wayrilz

Description

Wayrilz (rilzabrutinib)

Background
Wayrilz (rilzabrutinib) is a small-molecule, covalent, reversible kinase inhibitor targeting Bruton's tyrosine kinase (BTK). Wayrilz mediates its therapeutic effect in immune thrombocytopenia (ITP) through immune modulation including inhibition of B cell activation and interruption of antibody-coated cell phagocytosis by Fc-gamma receptor in spleen and liver. In vitro, Wayrilz reduced autoantibody signaling mediated through the Fc-gamma receptor pathway, blocked B cell signaling, and decreased autoantibody generation through effects on B cell activation (1).

Regulatory Status
FDA-approved indication: Wayrilz is a kinase 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 (1).

The use of this medication has been associated with serious infections, hepatotoxicity, and embryo-fetal toxicity. Monitor patients for signs and symptoms of infection, evaluate promptly, and treat. Evaluate bilirubin and transaminases at baseline and as clinically indicated during treatment. Based on animal studies, Wayrilz can cause fetal harm when administered to a pregnant woman. Verify pregnancy status of females of reproductive potential prior to initiating treatment. Advise females of reproductive potential to use effective contraception during treatment with Wayrilz and for at least 1 week after the last dose (1).

The safety and effectiveness of Wayrilz in pediatric patients less than 18 years of age have not been established (1).

Related policies
IVIG, Nplate, Tavalisse

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Wayrilz may be considered **medically necessary** if the conditions indicated below are met.

Wayrilz may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Persistent or chronic immune thrombocytopenia (ITP)

AND ALL of the following:

1. Inadequate response to at least **ONE** of the following therapies:
    a. Corticosteroids
    b. Immunoglobulins
    c. Splenectomy
    d. Thrombopoietin receptor agonists
2. Baseline platelet count prior to initiation must be less than 50,000/mcL (50 x 10^9/L)
3. Prescriber agrees to monitor bilirubin and transaminases at baseline and as clinically indicated during treatment
4. **NO** dual therapy with thrombopoietin receptor agonists

Prior–Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Persistent or chronic immune thrombocytopenia (ITP)

AND ALL of the following:

1. Improvement in platelet count to 50,000/mcL (50 x 10^9/L) or greater
2. Prescriber agrees to monitor bilirubin and transaminases as clinically indicated
3. **NO** dual therapy with thrombopoietin receptor agonists

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity 800 mg daily

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Wayrilz is a kinase inhibitor indicated for the treatment of persistent or chronic immune thrombocytopenia (ITP). It is for patients who have had an inadequate treatment response to at least one prior therapy. Wayrilz has been associated with serious infections, hepatotoxicity, and embryo-fetal toxicity. The safety and effectiveness of Wayrilz in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Wayrilz while maintaining optimal therapeutic outcomes.

References

1. Wayrilz [package insert]. Cambridge, MA: Genzyme Corporation; August 2025.

Policy History

Date	Action
October 2025	Addition to PA
December 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.