

Specialty Guideline Management

Wayrilz

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Wayrilz	rilzabrutinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication¹

Wayrilz is indicated for the treatment of adult patients with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

Immune Thrombocytopenia:

- For initial requests: Untransfused platelet count
- For continuation requests: Current platelet count

Prescriber Specialties

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

Coverage Criteria

Immune Thrombocytopenia (ITP)¹

Authorization of 6 months may be granted to members with ITP who meet both of the following criteria:

- Member has had an inadequate response or intolerance to prior therapy (e.g., corticosteroids, immunoglobulins).
- Member has an untransfused platelet count at any point prior to the initiation of the requested medication of either of the following:
 - Less than $30 \times 10^9/L$
 - $30 \times 10^9/L$ 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

Immune Thrombocytopenia (ITP)¹

Authorization of 12 months may be granted for continued treatment in all members (including new members) who are currently receiving the requested medication and who are experiencing benefit from therapy from baseline (e.g., increased platelet count, maintenance of platelet count).

Appendix

Examples of Risk Factors for Bleeding (not all inclusive)^{2,3}

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

Reference number(s)
7158-A

References

1. Wayrilz [package insert]. Cambridge, MA: Genzyme Corporation; August 2025.
2. 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.
3. 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.