Drug Coverage Policy

Effective Date.....03/01/2026
Coverage Policy Number.....IP0774
Policy Title.....Wayrilz

Thrombocytopenia – Wayrilz

- Wayrilz™ (rilzabrutinib tablets – Sanofi/Genzyme)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

Guidelines
Wayrilz is not addressed in guidelines. In 2019, the American Society of Hematology updated guidelines for ITP[2] with a subsequent review in 2022[3]. There are several recommendations. For adults with ITP for at least 3 months who are corticosteroid-dependent or unresponsive to corticosteroid, a thrombopoietin receptor agonist (either Promacta® [eltrombopag tablets and oral suspension, generic] or Nplate® [romiplostim subcutaneous injection]) or a splenectomy are recommended. Other noted treatment options in children and adults include intravenous immunoglobulin, anti-D immunoglobulin, and rituximab.

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POLICY STATEMENT
Prior Authorization is required for benefit coverage of Wayrilz. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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, approval requires Wayrilz to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information.

Wayrilz is considered medically necessary when the following are met:

FDA-Approved Indication

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, iv, and v):
     - **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 x 10^9/L (< 30,000/mcL) **[documentation required]**; OR
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)** Patient has a platelet count < 50 x 10^9/L (< 50,000/mcL) **[documentation required]**; 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 **[documentation required]**; OR
         Note: Examples of therapies are systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Promacta (eltrombopag olamine tablets and oral suspension), Alvaiz (eltrombopag choline tablets), Nplate (romiplostim

subcutaneous injection), Doptelet (avatrombopag tablets), Doptelet Sprinkle (avatrombopag oral granules) Tavalisse (fosmatanib tablets), or rituximab.

b) Patient has undergone splenectomy **[documentation required]**; AND

iv. The medication is prescribed by or in consultation with a hematologist; AND

v. Preferred product criteria is met for the product(s) as listed in the below table(s); 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.

Employer Plans:

Product	Criteria
Wayrilz (rilzabrutinib tablets)	Patient meets ONE of the following (1 or 2): **1.** Patient has tried eltrombopag olamine (tablets/oral suspension, generic Promacta); OR **2.** Patient is currently receiving Wayrilz

Individual and Family Plans:

Product	Criteria
Wayrilz (rilzabrutinib tablets)	Patient meets ONE of the following (1 or 2): **1.** Patient has tried eltrombopag olamine (tablets/oral suspension, generic Promacta); OR **2.** Patient is currently receiving Wayrilz

Conditions Not Covered

Wayrilz for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

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.
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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	03/01/2026

The policy effective date is in force until updated or retired.