VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Thrombocytopenia – Wayrilz Prior Authorization Policy
- Wayrilz™ (rilzabrutinib tablets – Sanofi/Genzyme)

REVIEW DATE: 09/03/2025

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.

POLICY STATEMENT

Prior Authorization is recommended for prescription 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

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, 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 x 10^9/L (< 30,000/mcL); 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); 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

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; 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Wayrilz is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/03/2025