PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/03/2025

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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

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is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

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is(are) considered not medically necessary for ANY other use(s). 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