

Prior Authorization Checklist

This checklist highlights items and information that may be needed to obtain a prior authorization (PA) decision from an insurer

Notice: This guide is provided for informational purposes only and does not constitute legal or reimbursement advice. It is not intended to substitute for the physician's independent diagnosis or treatment of each patient. The information contained herein is gathered from various resources and is subject to change. Providers are solely responsible for the accuracy of all coding and claims submitted for coverage or reimbursement to any third-party payer.

INDICATION

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.

Please see Important Safety Information on final page and full [Prescribing Information](#).

WAYRILZ[™]
(rilzabrutinib) 400 mg
tablets

Helping Your Patients Get Coverage for WAYRILZ

When a first-in-class immune thrombocytopenia (ITP) treatment like WAYRILZ™ (rilzabrutinib) is approved by the FDA, the coverage-approval process often requires healthcare providers (HCPs) or a member of their staff to submit a PA request to the patient's health insurance before receiving approval to initiate treatment.

HCPs or office staff may consider taking the following steps when seeking coverage approval



Review the PA policies and processes of each health plan

Health plans often have specific PA policies for specialty drugs, which can be viewed on their websites. PA requirements vary by plan and can be required for any treatment or prescription.



Complete and submit a PA request form

PA requests can often be submitted directly through a health plan's website or by completing downloadable forms. In some cases, it is necessary to contact the health plan directly and request a PA form.

Successfully completing the PA process may be an important step in helping your patients get the treatment they need

Note: Many insurers use a pharmacy benefits manager (PBM) for managing patient prescription benefits. Keep in mind, when a prescriber or a member of their office staff is submitting a PA, he or she may be communicating with the PBM and not the insurer.

FDA, US Food and Drug Administration.

IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS

Serious Infections: An increased risk of serious infections (including bacterial, viral, or fungal) can occur in patients treated with Bruton's tyrosine kinase (BTK) inhibitors, including WAYRILZ. Fatal pneumonia occurred in one participant treated with WAYRILZ in the LUNA-3 trial. Other serious infections [one each (0.8%)] included COVID-19 infection, wound infection, urinary tract infection and kidney abscess. Monitor patients for signs and symptoms of infection and treat appropriately.

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Provide Supporting Documentation

Letter of intent (LOI)

- Submission of an LOI to prescribe WAYRILZ is recommended with an initial PA request

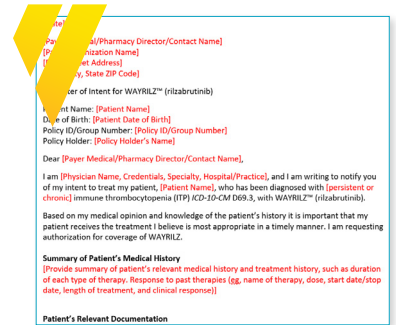
The WAYRILZ LOI contains

WAYRILZ indication

Planned dosing regimen

Intended treatment plan

Request for immediate WAYRILZ coverage authorization or the opportunity to discuss in a peer-to-peer review



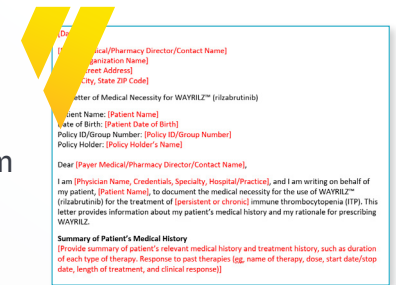
Letter of Intent

Letter of medical necessity (LMN)

- Submission of an LMN, which outlines the medical need for WAYRILZ, is recommended alongside the LOI

The WAYRILZ LMN contains

- Patient name, date of birth, insurance policy, and group number
- Diagnosis of ITP with appropriate *ICD-10-CM* code (D69.3)
- Relevant clinical data supporting the diagnosis, including current symptom severity, comorbidities, and intolerance to other therapies
- WAYRILZ dosing regimen and NDC number
- HCP's name, office address, and contact information
- Any other relevant information that may help the approval process, including
 1. Recent symptoms and condition
 2. Previously administered treatment(s)/procedure(s) and dates
 3. Response to the intervention(s)
 4. Physician opinion of patient prognosis or disease progression



Letter of Medical Necessity

To make the PA process go as smoothly as possible, it is very important to make sure all documentation is submitted with the initial PA request form

IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS (cont'd)

Hepatotoxicity, Including Drug-Induced Liver Injury (DILI): Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of DILI, can occur in patients treated with BTK inhibitors. Elevations of liver transaminases occurred with WAYRILZ in the ITP clinical trials and were generally mild to moderate in severity. Evaluate bilirubin and transaminases at baseline and as clinically indicated during treatment with WAYRILZ. For patients who develop abnormal liver tests after WAYRILZ, monitor more frequently. If DILI is suspected, withhold WAYRILZ. Upon confirmation of DILI, discontinue WAYRILZ.

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Handling Potential PA Request Denials

Common reasons for coverage denials include

1

Lack of demonstrated medical necessity

3

Incorrect or missing information

2

Out-of-network provider

4

Administrative errors

Steps to take if a PA request is denied

- HCPs or a member of their office staff have the option to appeal

To prepare for an appeal

Revisit the health plan's submission requirements and confirm that the initial claim was submitted correctly

Review the health plan's appeal process and deadlines

Note: The deadline for appealing a denial is usually 6 months

Please contact the payer to request the appeal form and verify any documentation requirements

Complete any required payer-specific appeal forms, along with the WAYRILZ Letter of Appeal and supporting documentation, to support the medical necessity and rationale for treating the patient with WAYRILZ

For more support with the PA process contact your Sanofi representative or call 1-833-723-5463 Option 3

The recommendations offered in this document do not guarantee approval of PA requests or reimbursement, nor should they be construed as medical advice. Always consult with patients' insurers/pharmacy benefit managers regarding specific requirements for PA submission.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Embryo-Fetal Toxicity: Based on findings from preliminary animal reproduction studies, WAYRILZ may cause fetal harm when administered to a pregnant woman. Verify pregnancy status of females of reproductive potential prior to initiating WAYRILZ treatment. Advise females of reproductive potential to use effective contraception while taking WAYRILZ and for 1 week after the final dose.

Please see Important Safety Information on final page and full [Prescribing Information](#).

Support for Your Patients From HemAssist

We complement the support you provide your WAYRILZ patients with financial assistance from Sanofi

Copoly Assistance Program ^a	HemAssist may be able to help eligible patients gain access to WAYRILZ for as little as \$0 copay per fill
Free Trial Program ^b	Patients can receive their first month supply of treatment with an enrollment form and valid prescription
Patient Assistance Program ^b	HemAssist's Patient Assistance Program may be available to help eligible WAYRILZ patients who are uninsured, underinsured, or experiencing a temporary loss of insurance coverage

To explore how HemAssist supports you and your patients in accessing, starting, and adhering to prescribed treatments, visit HCP.SanofiHemAssist.com.

^aNot valid if the patient is utilizing a state or federally funded health insurance program such as Medicare (including Medicare Part D), Medicaid, Medigap, VA, DOD, TRICARE®, state pharmaceutical assistance program, etc. to pay in part or in full for their WAYRILZ prescription. Not valid where prohibited by law. Sanofi reserves the right to modify or terminate the Copay Program at any time without notice. Savings by patients may vary depending on their out-of-pocket costs. The Program is intended to help patients afford their WAYRILZ prescription. Patients may have insurance plans that attempt to dilute the impact of the assistance available under the Program. In those situations, the Program may change its terms.

^bFree Trial valid only for a patient's first prescriptions, and it is limited to one use per patient per product for their lifetime. Free Trial not valid in Vermont. Claims for free products dispensed through the Free Trial or Patient Assistance Programs shall not be submitted to any third-party payer, public or private (eg, private insurance, Medicaid, Medicare, VA, DOD, TRICARE®, or similar federal or state programs) for reimbursement. All Programs not valid where prohibited by law. Sanofi reserves the right to modify or terminate the Programs at any time without notice. Program details provided upon registration.

DOD, Department of Defense; VA, Veterans Affairs.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

Most common adverse reactions reported (incidence ≥10%) were diarrhea, nausea, headache, abdominal pain, and COVID-19.

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DRUG INTERACTIONS

- Avoid concomitant use of WAYRILZ with strong or moderate CYP3A inhibitors, which increases the risk of WAYRILZ adverse reactions. If short term use of these inhibitors cannot be avoided, interrupt treatment with WAYRILZ. Avoid concomitant use of grapefruit, starfruit and products containing these fruits, and Seville oranges with WAYRILZ.
- Avoid concomitant use with a strong or moderate CYP3A inducer, which may reduce WAYRILZ efficacy.
- Administer the dose of WAYRILZ at least 2 hours before administration of an antacid or histamine H2 receptor antagonist. Avoid concomitant use of proton pump inhibitors with WAYRILZ. Concomitant use of acid reducing agents may reduce WAYRILZ efficacy.
- Rilzabrutinib is a moderate inhibitor of CYP3A and increases exposure of these substrates. Monitor for adverse reactions and consider dosage adjustment of the CYP3A substrate.
- Rilzabrutinib is an inhibitor of P-gp, BCRP and OATP1B *in vitro*. The effect of concomitant use of WAYRILZ with OATP1B and BCRP substrates has not been established in clinical studies. Monitor for adverse reactions of the concurrently administered P-gp, BCRP, or OATP1B substrate more frequently where minimal substrate concentration changes may lead to serious adverse reactions.

USE IN SPECIFIC POPULATIONS

- **Lactation:** Due to the potential for adverse reactions in a breastfed child, advise lactating women not to breastfeed while taking WAYRILZ and for at least 1 week after the final dose
- **Hepatic Impairment:** Avoid administration of WAYRILZ in patients with moderate or severe hepatic impairment (Child-Pugh class B-C)
- **Renal Impairment:** Avoid use in patients with severe renal impairment

Please see full [Prescribing Information](#).

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