Mimrylo™
rusfertide for injection

Access Guide

Navigating the process of health plan coverage approval can be complex and time consuming. This access guide will help you and your patients with polycythemia vera (PV) understand and manage the various MIMRYLO™ (rusfertide) coverage scenarios that may be encountered throughout the insurance journey.

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INDICATION

MIMRYLO is indicated for the treatment of erythrocytosis in adults with polycythemia vera (PV).

Please see additional Important Safety Information on page 8 and accompanying full Prescribing Information.

Takeda | ONCOLOGY

MIMRYLO is a first-in-class hepcidin mimetic for the treatment of erythrocytosis in patients with polycythemia vera[1]

How MIMRYLO is supplied[2]

- MIMRYLO for injection is supplied in a carton for each individual dosage strength comprising a single-dose vial containing a sterile, preservative-free, white to off-white lyophilized powder and a single-dose prefilled syringe containing a clear, colorless solution (diluent) with a luer-lock adapter and soft inner tip cap
- Not made with natural rubber latex

Dosage Strength(per vial)	Color Cap Indicator	Carton NDC Number
9.5 mg/vial	Blue	63020-715-10
19 mg/vial*	Lime	63020-725-20
28 mg/vial	Burgundy	63020-735-30
41 mg/vial	Yellow	63020-745-40
54 mg/vial	White	63020-765-60

*The recommended starting dose of MIMRYLO is 19 mg SC injection once a week.[2]

Specialty pharmacies will ship a **Welcome Kit** to each new MIMRYLO patient to help them get organized and reinforce injection training. It includes:

- Patient Brochure
- MIMRYLO Patient Support Flashcard
- Dosing and Administration Guide
- Step-by-Step Injection Guide
- Demonstration Kit
- Injection Placemat

For further information, please view the Welcome Kit information

Please ensure your systems are updated with the above NDCs and product details

NDC, National Drug Code.

Please see Important Safety Information on page 8 and accompanying full Prescribing Information.

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Storage and handling[2]

- Store at room temperature between 68°F and 77°F (20°C to 25°C)
- Do not freeze
- Store in the original carton to protect from light
- Do not use the vial or the diluent prefilled syringe after the expiration date on the labels
- After reconstitution, administer MIMRYLO immediately or use within 4 hours
- Discard reconstituted solution if not used within 4 hours

Recommended dosing[2]

- For subcutaneous use only
- Recommended starting dose: 19 mg once a week
- Dose of MIMRYLO may be adjusted based on efficacy and safety
- Maximum daily dose is 82 mg and maximum weekly dose is 108 mg
- Monitor complete blood count (CBC) every 2 to 4 weeks or as clinically indicated during dose modifications

ORDERING AND DISTRIBUTION

MIMRYLO is available through both specialty pharmacies and practices that dispense.

Ordering through Specialty Distributors
(Qualified entities* only)

MIMRYLO may be purchased through the following distribution partners and dispensed at accounts that have a medically integrated pharmacy:

Cardinal Health
Monday–Friday: 7:00 am - 6:00 pm CT
1-855-855-0708
1-866-677-4844 (on call/after hours)
Website: https://vantus.cardinalhealth.com/home

Oncology Supply
Phone: 1-800-633-7555
Fax: 1-800-248-8205
Email: service@oncologysupply.com

ASD Healthcare
Monday–Thursday: 7:00 am - 6:30 pm CT
Friday: 7:00 am - 6:00 pm CT
Phone: 1-800-746-6273
Fax: 1-800-547-9413
Email: service@asdhealthcare.com

McKesson Plasma and Biologics
Phone: 1-877-625-2566
Fax: 1-888-752-7626
Email: mpborders@mckesson.com
Online ordering portal: connect.mckesson.com

McKesson Specialty Health
Phone: 1-800-482-6700
Fax number: 1-855-824-9489
Email: oncologycustomersupport@mckesson.com
Online ordering portal: mscs.mckesson.com

Ordering through Specialty Pharmacies

Choose one of the following specialty pharmacies in the MIMRYLO network:

Biologics
Phone: 1-800-850-4306
Fax: 1-800-823-4506
E-prescription (if applicable): NPI 1487640314; NCPDP 3430369
Website: biologics.mckesson.com

Onco360
Phone: 1-877-662-6633
Fax: 1-877-662-6355
E-prescription (if applicable): NPI 1679618151
Website: www.onco360.com

In-Office Dispensing
To arrange in-office dispensing, please contact your specialty distributor or Takeda Oncology Here2Assist® at 1-844-817-6468, Option 5, Monday–Friday, 8:00 am - 8:00 pm ET

If your institution does not have medically integrated dispensing capabilities or chooses not to fill a MIMRYLO prescription through your medically integrated pharmacy, MIMRYLO may be ordered and filled through one of these in-network specialty pharmacies. Sending a MIMRYLO prescription to a pharmacy that is either not your institution's medically integrated pharmacy or outside of the limited distribution network may result in delay or nonfulfillment of the prescription.

Please contact your Takeda Representative with any questions you may have

CT; Central Time, ET, Eastern Time; NCPC, National Council for Prescription Drug Programs; NPI, National Provider Identifier.

*Qualified entities for direct purchase include hospitals, physician practices, and institutions that have been licensed by a state agency to dispense pharmaceutical products to appropriate patients. Direct purchase is not available to specialty pharmacy providers or retail pharmacies who are not themselves part of a qualified entity. Eligible government entities include the Department of Defense (DoD), Department of Veterans Affairs, and 340B-covered entities.

Please see Important Safety Information on page 8 and accompanying full Prescribing Information.

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BILLING AND CODING

CPT Code[3]

This CPT Code may be used to identify subcutaneously injected drugs administered in an office or institutional setting (eg, for the patient's first dose).

CPT Code	Description
96372	Therapeutic, prophylactic, or diagnostic injection (subcutaneous/intramuscular)

Diagnosis Code[4]

ICD-10-CM	Description
D45	Polycythemia vera

CPT, Current Procedural Terminology; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.

Takeda Oncology Here2Assist®

Takeda Oncology Here2Assist® is a **comprehensive support program** committed to helping patients navigate **coverage requirements**, identify available **financial assistance**, provide expert care and guidance with nurse-led **injection trainings**, and connect patients with helpful resources throughout their treatment.

Questions about enrolling in our support program?
We have the answers.

Models are used for illustrative purposes only.

Let's Talk. Call us at 1-844-817-6468, Option 2. We're available Monday-Friday, 8am-8pm ET

Enroll online at **www.Here2Assist.com**

Takeda Oncology Here2Assist®

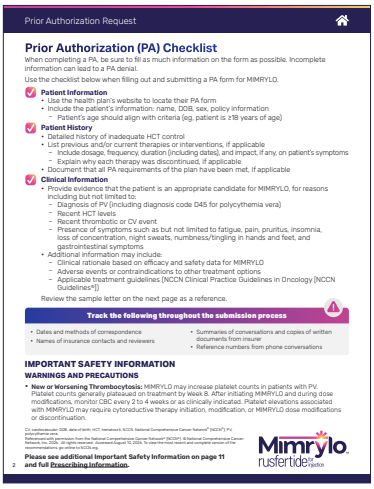
PRIOR AUTHORIZATION AND APPEALS RESOURCES

Depending on a patient's prescription drug benefit, you may be required to submit a PA before your patient can receive treatment with MIMRYLO. Each health plan has different requirements, so calling and confirming their policy is recommended. Sometimes PAs are denied. In those circumstances, you and your patient can appeal the decision.

It is important to understand why the PA was denied in the first place. Some common reasons for denial:

- Missing or inaccurate information
- Step-edit requirement
- Incorrect diagnosis code(s) submitted
- Billed to the wrong benefit (ie, medical vs pharmacy)
- Not covered on the formulary

These resources are at your disposal to assist with the PA process for MIMRYLO:


Prior Authorization Request

Prior Authorization (PA) Checklist

When completing a PA, be sure to fill as much information on the form as possible. Incomplete information can lead to a PA denial.

Use the checklist below when filling out and submitting a PA form for MIMRYLO.

- **Patient Information**
  - Use the health plan's website to locate their PA form
  - Include the patient's information: name, DOB, sex, policy information
    - Patient's age should align with criteria (eg, patient is ≥18 years of age)
- **Patient History**
  - Detailed history of inadequate HCT control
  - List previous and/or current therapies or interventions, if applicable
    - Include dosage, frequency, duration (including dates), and impact, if any, on patient's symptoms
    - Explain why each therapy was discontinued, if applicable
  - Document that all PA requirements of the plan have been met, if applicable
- **Clinical Information**
  - Provide evidence that the patient is an appropriate candidate for MIMRYLO, for reasons including but not limited to:
    - Diagnosis of PV (including diagnosis code D45 for polycythemia vera)
    - Recent HCT levels
    - Recent thrombotic or CV event
    - Presence of symptoms such as but not limited to fatigue, pain, pruritus, insomnia, loss of concentration, night sweats, numbness/tingling in hands and feet, and gastrointestinal symptoms
  - Additional information may include:
    - Clinical rationale based on efficacy and safety data for MIMRYLO
    - Adverse events or contraindications to other treatment options
    - Applicable treatment guidelines [NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)]

Review the sample letter on the next page as a reference.

Track the following throughout the submission process

- Dates and methods of correspondence
- Names of insurance contacts and reviewers
- Summaries of conversations and copies of written documents from insurer
- Reference numbers from phone conversations

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **New or Worsening Thrombocytosis:** MIMRYLO may increase platelet counts in patients with PV. Platelet counts generally plateaued on treatment by Week 8. After initiating MIMRYLO and during dose modifications, monitor CBC every 2 to 4 weeks or as clinically indicated. Platelet elevations associated with MIMRYLO may require cytoreductive therapy initiation, modification, or MIMRYLO dose modifications or discontinuation.

CV, cardiovascular; DOB, date of birth; HCT, hematocrit; NCCN, National Comprehensive Cancer Network® (NCCN®); PV, polycythemia vera.

References:1.with permission from the National Comprehensive Cancer Network® (NCCN®). © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 13, 2024. To view the most recent and complete version of the recommendations, go online to NCCN.org.

Please see additional Important Safety Information on page 11 and full Prescribing Information.

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PA Checklist

Be prepared for every submission.


Formulary Exception Request

Formulary Exception Request Letter Checklist

When sending a formulary exception request letter be sure to include as much clarifying information within as possible. Incomplete information can lead to denial.

Use the checklist below when sending a formulary exception request letter for MIMRYLO.

- **Patient Information**
  - Include the patient's information: name, DOB, sex, policy information
  - Note that the purpose of this letter is the patient is requesting an exception to the formulary to fill their prescription for MIMRYLO
- **Patient History**
  - List previous therapy/therapies
    - If applicable, explain why each therapy was discontinued and give the duration of therapy for each agent
  - If other agents/treatments are not appropriate for this patient, explain why not (if they have not already been listed as previous therapies)
- **Clinical Information**
  - Include diagnosis and specific diagnosis code for PV where appropriate [D45 for polycythemia vera]
  - Provide rationale and clinical support for your reason(s) for requesting this formulary exception
  - Provide a phone number should additional information be required to answer any questions or to participate in a peer-to-peer review discussing the necessity of providing a formulary exception for the use of MIMRYLO for this patient
- **Additional Information**
  - Include physician signature at the bottom of the letter
  - If this is a second- or third-level appeal for formulary exception, include level of appeal, letter of denial, and medical notes in response to denial

Review the sample letter on the next page as a reference.

Track the following throughout the submission process

- Dates and methods of correspondence
- Names of insurance contacts and reviewers
- Summaries of conversations and copies of written documents from insurer
- Reference numbers from phone conversations

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

The most common (>20%) adverse reactions were injection site reactions (56%) and anemia (16%).

Please see additional Important Safety Information on page 11 and full Prescribing Information.

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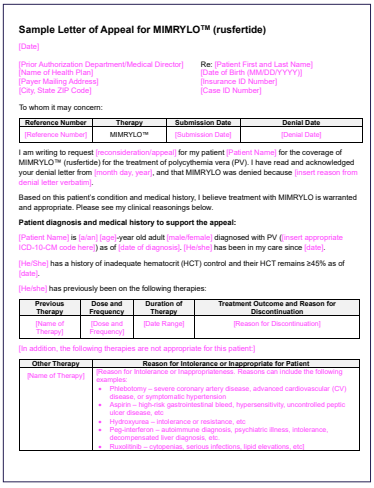
Formulary Exception Guide

Navigate the Medical Exception process to obtain drug coverage for your patients with PV.


Sample Letter of Appeal for MIMRYLO™ (rusfertide)

[Date]

[Prior Authorization Department/Medical Director]
[Name of Health Plan]
[Payer Mailing Address]
[City, State ZIP Code]

Re: [Patient First and Last Name]
[Date of Birth (MM/DD/YYYY)]
[Insurance ID Number]
[Case ID Number]

To whom it may concern:

Reference Number	Therapy	Submission Date	Denial Date
[Reference Number]	MIMRYLO™	[Submission Date]	[Denial Date]

I am writing to request [reconsideration/appeal] for my patient [Patient Name] for the coverage of MIMRYLO™ (rusfertide) for the treatment of polycythemia vera (PV). I have read and acknowledged your denial letter from [month day, year], and that MIMRYLO was denied because [insert reason from denial letter verbatim].

Based on this patient's condition and medical history, I believe treatment with MIMRYLO is warranted and appropriate. Please see my clinical reasonings below.

Patient diagnosis and medical history to support the appeal:

[Patient Name] is [a/an] [age]-year old adult [male/female] diagnosed with PV ([insert appropriate ICD-10-CM code here]) as of [date of diagnosis]. [He/She] has been in my care since [date].

[He/She] has a history of inadequate hematocrit (HCT) control and their HCT remains ≥45% as of [date].

[He/she] has previously been on the following therapies:

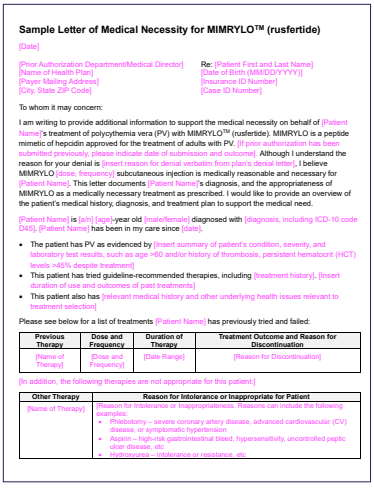
Previous Therapy	Dose and Frequency	Duration of Therapy	Treatment Outcome and Reason for Discontinuation
[Name of Therapy]	[Dose and Frequency]	[Date Range]	[Reason for Discontinuation]

[In addition, the following therapies are not appropriate for this patient:]

Other Therapy	Reason for Intolerance or Inappropriate for Patient
[Name of Therapy]	[Reason for Intolerance or Inappropriateness. Reasons can include the following examples: • Phlebotomy – severe coronary artery disease, advanced cardiovascular (CV) disease, or symptomatic hypertension • Aspirin – high-risk gastrointestinal bleed, hypersensitivity, uncontrolled peptic ulcer disease, etc • Hydroxyurea – intolerance or resistance, etc • Peg-interferon – autoimmune diagnosis, psychiatric illness, intolerance, decompensated liver diagnosis, etc • Ruxolitinib – cytopenias, serious infections, lipid elevations, etc]

Sample Appeal Letter

This letter can be used as a guide when the appeal needs to clearly answer the reason for denial and explain the healthcare professional's clinical rationale.


Sample Letter of Medical Necessity for MIMRYLO™ (rusfertide)

[Date]

[Prior Authorization Department/Medical Director]
[Name of Health Plan]
[Payer Mailing Address]
[City, State ZIP Code]

Re: [Patient First and Last Name]
[Date of Birth (MM/DD/YYYY)]
[Insurance ID Number]
[Case ID Number]

To whom it may concern:

I am writing to provide additional information to support the medical necessity on behalf of [Patient Name]'s treatment of polycythemia vera (PV) with MIMRYLO™ (rusfertide). MIMRYLO is a peptide mimetic of hepcidin approved for the treatment of adults with PV. [If prior authorization has been submitted previously, please indicate date of submission and outcome]. Although I understand the reason for your denial is [insert reason for denial verbatim from plan's denial letter], I believe MIMRYLO [dose, frequency] subcutaneous injection is medically reasonable and necessary for [Patient Name]. This letter documents [Patient Name]'s diagnosis, and the appropriateness of MIMRYLO as a medically necessary treatment as prescribed. I would like to provide an overview of the patient's medical history, diagnosis, and treatment plan to support the medical need.

[Patient Name] is [a/an] [age]-year old [male/female] diagnosed with [diagnosis, including ICD-10 code D45]. [Patient Name] has been in my care since [date].

- The patient has PV as evidenced by [insert summary of patient's condition, severity, and laboratory test results, such as age >60 and/or history of thrombosis, persistent hematocrit (HCT) levels >45% despite treatment]
- This patient has tried guideline-recommended therapies, including [treatment history], [insert duration of use and outcomes of past treatments]
- This patient also has [relevant medical history and other underlying health issues relevant to treatment selection]

Please see below for a list of treatments [Patient Name] has previously tried and failed:

Previous Therapy	Dose and Frequency	Duration of Therapy	Treatment Outcome and Reason for Discontinuation
[Name of Therapy]	[Dose and Frequency]	[Date Range]	[Reason for Discontinuation]

[In addition, the following therapies are not appropriate for this patient:]

Other Therapy	Reason for Intolerance or Inappropriate for Patient
[Name of Therapy]	[Reason for Intolerance or Inappropriateness. Reasons can include the following examples: • Phlebotomy – severe coronary artery disease, advanced cardiovascular (CV) disease, or symptomatic hypertension • Aspirin – high-risk gastrointestinal bleed, hypersensitivity, uncontrolled peptic ulcer disease, etc • Hydroxyurea – intolerance or resistance, etc

Sample Letter of Medical Necessity

A Letter of Medical Necessity supports the PA process by explaining the clinical rationale for MIMRYLO.

For further support, please reference MIMRYLO's Prior Authorization Kit

PA, prior authorization.

Please see Important Safety Information on page 8 and accompanying full Prescribing Information.

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COVERAGE RESOURCES

MIMRYLO coverage requirements may vary by plan. The first questions patients may have are whether their health insurance covers MIMRYLO and how much it will cost.

Benefits investigation

A benefits investigation can uncover these answers. Call the patient's health plan on their behalf to determine coverage and out-of-pocket costs. Be sure to have your patient's insurance information, including any secondary insurance, to get the process started.

MIMRYLO may be covered under the pharmacy benefit. This benefit design can impact how MIMRYLO is acquired and reimbursed.

Understanding medication coverage

If your patient needs assistance understanding medication coverage, you can share this "Guide to Medication Coverage"

Guide to Medication Coverage

Understand your medication coverage and learn about changes to Medicare Part D.

For further information, please view the Guide to Medication Coverage

Please contact your Takeda Field Reimbursement Director (FRD) for matters related to access and reimbursement

INDICATION

MIMRYLO is indicated for the treatment of erythrocytosis in adults with polycythemia vera (PV).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **New or Worsening Thrombocytosis:** MIMRYLO may increase platelet counts in patients with PV. Platelet counts generally plateaued on treatment by Week 8. After initiating MIMRYLO and during dose modifications, monitor CBC every 2 to 4 weeks or as clinically indicated. Platelet elevations associated with MIMRYLO may require cytoreductive therapy initiation, modification, or MIMRYLO dose modifications or discontinuation.
- **Injection-Site Reactions:** Injection site reactions (including Grade 3 reactions) have been reported in patients treated with MIMRYLO. The most common injection site reactions reported were erythema, pruritus, pain, and swelling. Use ice, topical corticosteroid creams, antihistamines or analgesics, as needed, to treat injection site pain and swelling.
- **Embryo-Fetal Toxicity:** Based on findings from animal reproduction studies, MIMRYLO may cause fetal harm when administered to a pregnant woman. Advise patients to stop taking MIMRYLO if they become pregnant.

ADVERSE REACTIONS

The most common (>15%) adverse reactions were injection site reactions (56%) and anemia (16%).

USE IN SPECIFIC POPULATIONS

- **Lactation:** Because of the potential for serious adverse reactions in the breastfed child, including impaired iron absorption, advise patients not to breastfeed during treatment with MIMRYLO and for 30 days after the final treatment.
- **Females and Males of Reproductive Potential**
  - **Pregnancy Testing:** Prior to initiating MIMRYLO, pregnancy testing is recommended for females of reproductive potential.
  - **Contraception**: Advise female patients of reproductive potential to use effective contraception during treatment with MIMRYLO and for at least 30 days after the final dose of MIMRYLO.

To report SUSPECTED ADVERSE REACTIONS, contact Takeda Pharmaceuticals at 1-844-662-8532 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying MIMRYLO (rusfertide) full Prescribing Information.

References: 1. Takeda Oncology. Accessed August 2026. https://www.takeda.com/newsroom/newsreleases/2025/new-drug-application-pv/ **2.** MIMRYLO. Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc.; 2026. **3.** Centers for Medicare & Medicaid Services. Search the Physician Fee Schedule: HCPCS code 96372. CMS. Accessed August 2026. https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&P=1&HT=0&CT=3&H1=96372&M=5 **4.** Centers for Medicare & Medicaid Services. ICD-10-CM/PCS MS-DRG v41.0 Definitions Manual. CMS. Accessed August 2026. https://www.cms.gov/icd10m/FY2024-version41-fullcode-cms/fullcode_cms/P1276.html

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