Mimrylo™ rusfertide for injection

Leveraging iKnowMed® EHR Capabilities

to Support the Treatment of Patients With Polycythemia Vera (PV)

EHR=electronic health record.

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.

Please see additional Important Safety Information throughout and on page 21. Please see MIMRYLO (rusfertide) full Prescribing Information.

Takeda

About This Guide

This instructional guide provides information to assist with updating the EHR to support MIMRYLO™ (rusfertide), a treatment option for patients with PV. It includes examples and steps to inform healthcare providers on including MIMRYLO in prescribing workflow capabilities.

This resource is meant to serve as summary information only and should not replace detailed instructions provided to you by your internal or external EHR support resources. Screen images shown within represent hypothetical screens in iKnowMed®. Takeda makes no claims or warranties about the applicability or appropriateness of this information.

This guide is meant to provide guidance for you, your office manager, your EHR champion, and information technology (IT) staff about MIMRYLO. It provides examples for discussion purposes only, does not constitute guidance or medical advice for treatment, and does not represent all workflows for implementation. It is ultimately the responsibility of the healthcare provider to select a treatment based on their independent medical judgment and the need of each individual patient and to determine and implement the appropriate workflows.

The instructions listed in this guide are for use with the most current version of iKnowMed systems. Although the instructions have been tested on this EHR system, they are not guaranteed to work for all available software versions. These materials have not been reviewed or endorsed by iKnowMed.

The user is solely responsible for the implementation, testing, and monitoring to ensure proper orientation in the EHR system.

IMPORTANT SAFETY INFORMATION (cont.)

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**
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About This Guide (cont.)

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Why This Matters

PV is a chronic myeloproliferative neoplasm (MPN) characterized by red blood cell overproduction that can lead to far reaching outcomes due to uncontrolled hematocrit (HCT), persistent symptom burden, and iron dysregulation.[1-7]

In a real-world study, 78% of patients were not able to consistently control HCT below 45% despite being on treatment.[2,3] In fact, only 14% of low-risk and 25% of high-risk patients consistently maintained HCT below 45% despite treatment with phlebotomy with or without cytoreductive therapy.[2]*

When HCT is even slightly elevated (45%-50%), people are 4x more likely to experience major thrombolytic events or CV death vs when HCT is <45%.[8]†

For many patients, increased symptom burden is more than discomfort; it can reduce overall survival in people with PV.[‡§4] In a retrospective study, approximately 60% of patients showed laboratory evidence of iron depletion (N=38).[6] Iron deficiency may persist or worsen with ongoing therapeutic phlebotomy, especially as erythrocytosis continues, and can lead to:[12-15]

- Fatigue
- Brain fog
- Physical inactivity
- Weakness and dizziness

The primary aim of PV management is to maintain HCT below the 45% threshold. Other treatment goals include:[8,10-11]

- Reducing the burden of phlebotomy
- Symptom reduction
- Delaying disease progression

Current PV treatment guidelines are focused on keeping HCT below the 45% threshold and monitoring disease progression but may not capture fluctuating HCT and associated risks.[5,10]

*Based on a retrospective, observational real-world study of 28,306 patients with PV initiating treatment in the US between 2011 and 2019. Real-world analyses often have limitations and include the potential for incomplete or missing records and misdiagnosis of PV, as diagnoses were based solely on database records. There is the possibility that thrombotic events were misdiagnosed, underdiagnosed, or otherwise, incorrectly reported. Outcomes and comparisons between studies should be interpreted with caution.[1]

†In an Italian RCT study (CYTO-PV) of 365 PV patients being treated with phlebotomy, hydroxyurea, or both, 2.7% (n=5/182) with HCT <45% died from CV causes or had major thrombotic events vs 9.8% (n=18/183) with HCT 45%-50%, after a median follow-up of 31 months (HR, 3.91; 95% CI, 1.45-10.53; P=0.007).[3]

‡Based on an analysis of PV patients with high symptom burden (defined as Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS] >35) [n=24] vs those with low symptom (P=0.002) burden (n=256).[9]

§A multicenter, retrospective, observational study comprising patients from 13 academic and community centers. Eligibility criteria were patients >18 years old, enrolled with a diagnosis of PV, ET or MF (primary or post-PV/ET) according to WHO and/or International Consensus criteria, and having completed at least one MPN-SAF TSS questionnaire between April 2013 and August 2022.[4]

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

- **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.

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Why This Matters (cont.)

Optimizing Workflow to Facilitate the Prescribing of MIMRYLO™ (rusfertide)

Updating EHR workflow can help address the potential for confusion around MIMRYLO dosing that can ultimately lead to delays.

MIMRYLO is initiated using a standardized starting approach. Based on individual patient response and tolerability, modification may be considered to support achievement or maintenance of the desired therapeutic effect (e.g., HCT <45%). Dose reduction may also be appropriate if clinically significant anemia or other treatment-related adverse events should occur.

When considering a dose adjustment, note that single-dose vials are available in 5 different strengths: 9.5 mg, 19 mg, 28 mg, 41 mg, and 54 mg. Therefore, some prescribed doses may require a combination of these vial strengths (e.g., 28 mg + 41 mg to achieve 69 mg) or increasing the quantity (e.g., 82 mg would require two 41 mg vials). In cases where different vial strengths are combined, 2 separate prescriptions will need to be written since the pharmacy will need to dispense 2 distinct kits. This guide includes instructions for creating an orderable item for doses requiring 2 separate strengths and therefore 2 separate prescriptions.

Dosing Overview: Matching Prescriptions to Intended Dose

Weekly Dose	Sample Sig	Number of Prescriptions Required
9.5 mg	Inject one 9.5 mg kit	1
19 mg	Inject one 19 mg kit	1
28 mg	Inject one 28 mg kit	1
41 mg	Inject one 41 mg kit	1
54 mg	Inject one 54 mg kit	1
69 mg	Inject one 28 mg kit and one 41 mg kit weekly	2 1x28 mg kit per week and 1x41 mg kit per week
82 mg	Inject two 41 mg kits weekly	1 2x41 mg kits per week
95 mg	Inject one 54 mg kit and one 41 mg kit weekly	2 1x54 mg kit per week and 1x41 mg kit per week
108 mg	Inject two 54 mg kits weekly	1 2x54 mg kits per week

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS

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Why This Matters (cont.)

EHR Tools to Address Dosing

This guide focuses on several EHR tools that can be beneficial to help ensure that the proper dose of MIMRYLO™ (rusfertide) is prescribed and adhered to, including:

- Regimen
- Patient Reports
- Alerts
- Patient education orders

IMPORTANT SAFETY INFORMATION (cont.)

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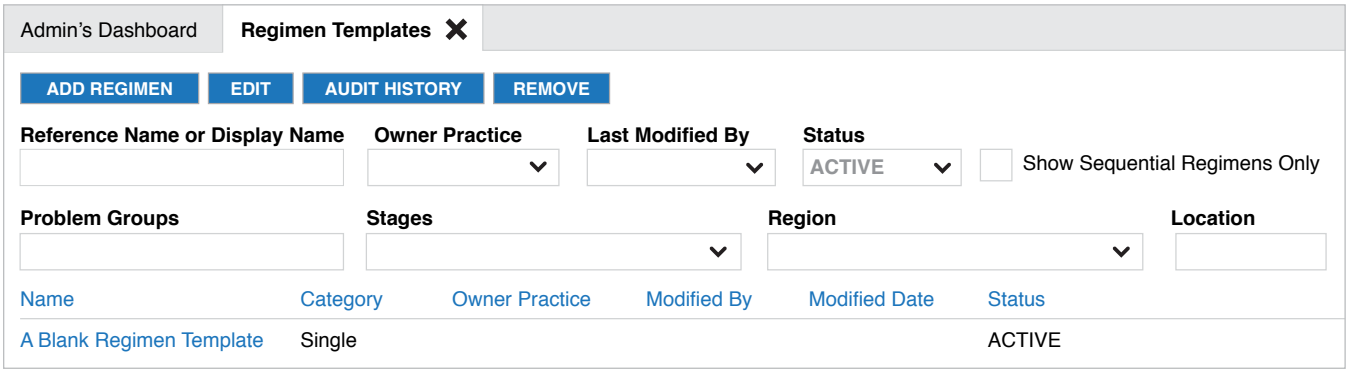
MIMRYLO™ (rusfertide) Regimen

Regimen Templates are commonly used to support the consistent ordering of therapies, associated monitoring, and supportive care elements across patient encounters. When configured, Regimen Templates can help:

- Promote standardization of care by prepopulating commonly ordered items for a given therapy or indication
- Reduce the risk of omissions or variability during ordering
- Streamline clinician workflows by organizing medications, labs, services, and other orderables in a structured manner
- Support downstream workflows such as scheduling, documentation, and reporting

Orders included in a regimen may be grouped and sequenced to reflect how care is typically delivered, while still allowing for clinician review and modification as clinically appropriate.

1. From the **Manage** menu, select **Regimen Templates**.
2. In the **Reference Name or Display Name** field, search for and select the Regimen to copy; for example, A Blank Regimen Template.



Example of Regimen Template Search

IMPORTANT SAFETY INFORMATION

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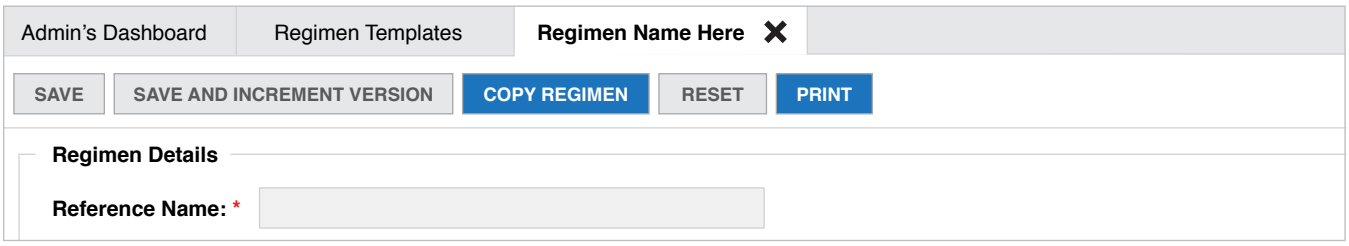
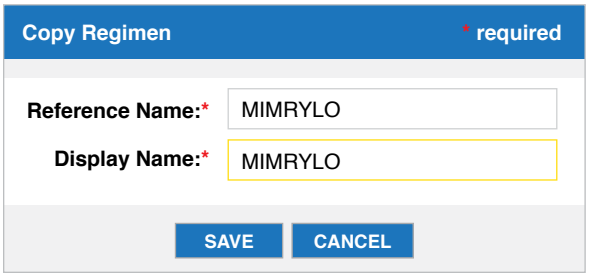
MIMRYLO™ (rusfertide) Regimen (cont.)

3. Select **Copy Regimen**.



Example of Regimen Option

4. Enter the new **Reference Name** (internal) and the **Display Name**; for example, MIMRYLO. Select **Save**.



Example of naming an additional Regimen

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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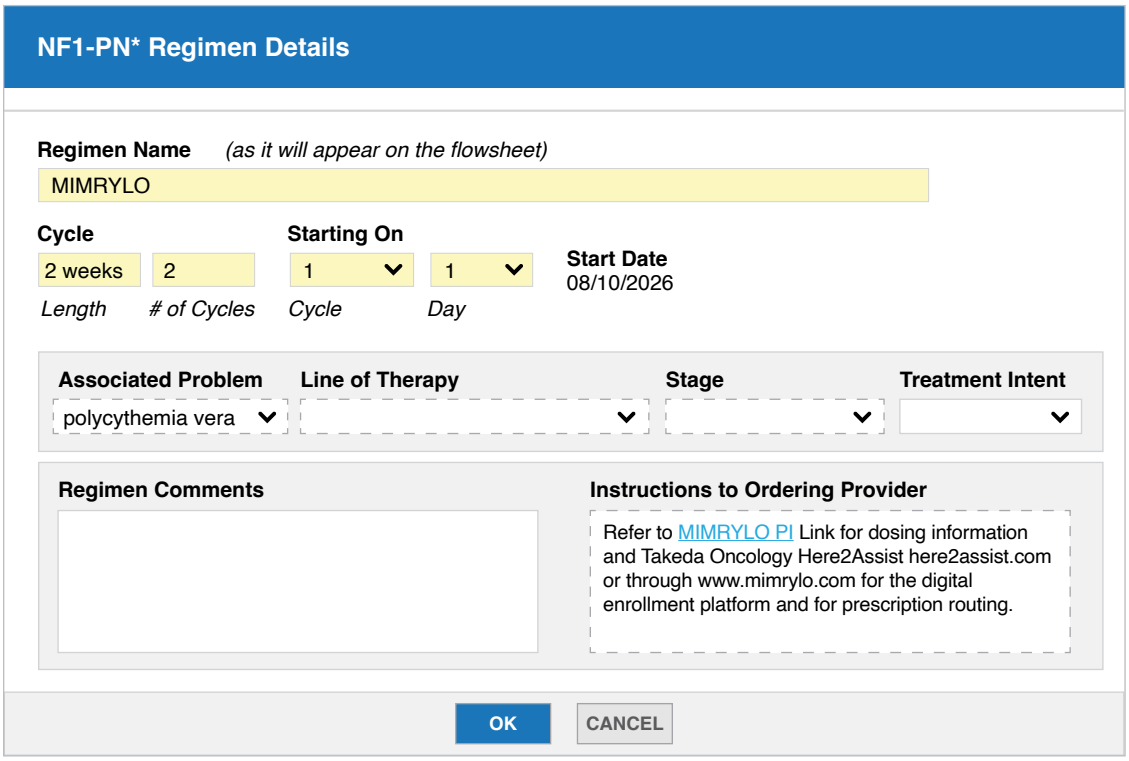
MIMRYLO™ (rusfertide) Regimen (cont.)

5. Search for and select the **Associated Problem**, such as polycythemia vera.
6. Define the **Regimen Rule Detail**; select **Save**.
7. Select **Add Rule**.
8. Complete the **Regimen Details** and select **OK**.



Example of Regimen Details window

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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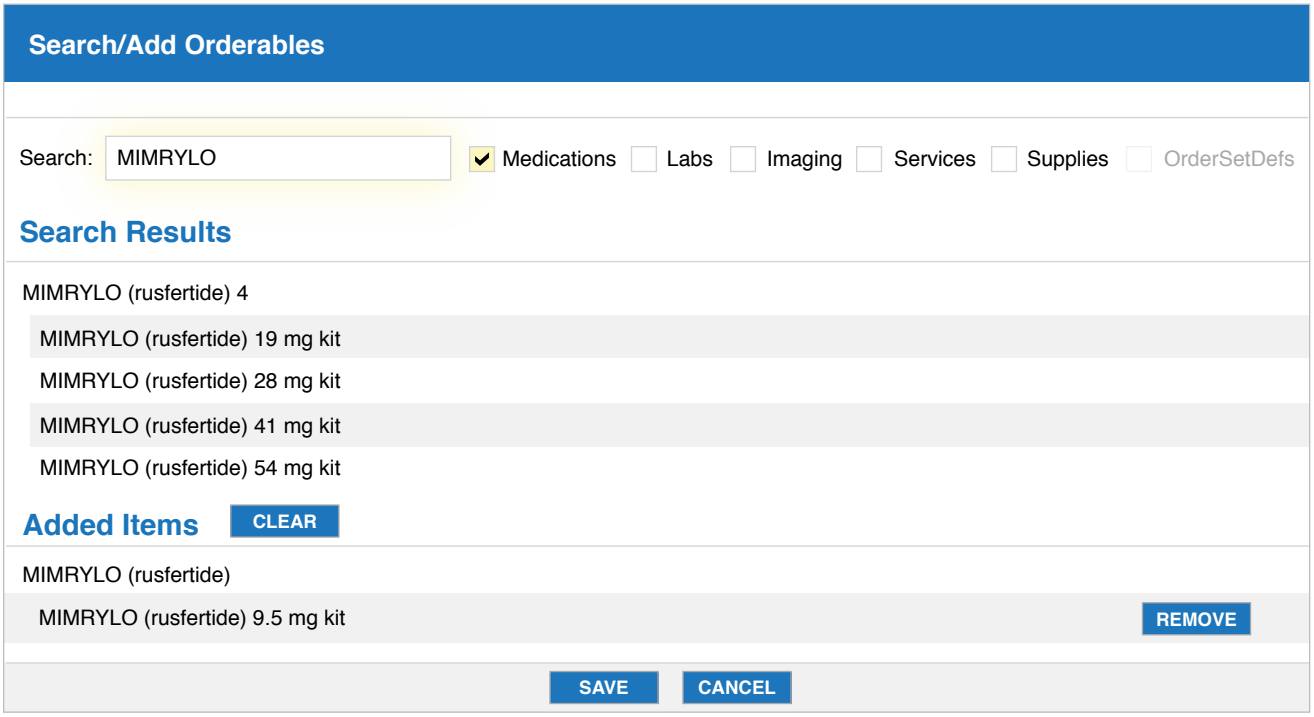
MIMRYLO™ (rusfertide) Regimen (cont.)

Adding Medications to the Regimen

1. In the **Regimen Items** list, add items, such as medication, to the Regimen by selecting **+ ADD GROUP**. Consider adding groups for Medications, Labs, and Services.
2. Select the **+** to the right of **Medications**. In the **Search/Add Orderables** window, search for MIMRYLO.
3. Select **MIMRYLO** to add it to the **Added Items** list, then select **Save**.



Example of the Search/Add Orderables

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS

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MIMRYLO™ (rusfertide) Regimen (cont.)

4. From the **Regimen Items** list, select the newly added MIMRYLO to open a detail window.

   Note: *Options selected here will default when the order is selected.*

5. Check **Rx** and **Formula Dose** to enter appropriate dosing instructions. Use the **Quick SIG Pick** or **Show Drug Forms** to display preset Dose, Frequency, and Form Instruction options. Select as desired.
6. In the **Instructions**, add appropriate medication details to ensure proper dosing is administered. Dosing for MIMRYLO is based on HCT results.
7. In the **Instructions to Pharmacist**, consider placing a comment indicating to send the order to Takeda Oncology Here2Assist here2assist.com or through www.mimrylo.com for the digital enrollment platform.

Adding Labs to the Regimen

1. From the list of **Regimen Items**, select or add the appropriate **Treatment Group**; for example, **Lab Orders**.
2. Select appropriate labs; for example, hematocrit (HCT) and add to the regimen.
3. Set appropriate timeframes for each lab; for example:
   a. At baseline prior to administration
   b. Every 2 weeks for 26 weeks

Adding Services to the Regimen

1. Select **+** to the right of **SERVICES**. In the **Search/Add Orderables** window, search for patient education and patient support program information.
2. From the **Regimen Items** list, select the newly added patient education and patient support program information to open a detail window.
3. In **Display As**, enter a descriptive name; for example, MIMRYLO Patient Education and Patient Support Program information.
4. In the **Schedule Info** section, select **EDIT**.

   Note: *Adding schedule information allows the item to display properly when added to the flowsheet.*

5. Define timeframes; for example, Today or Within 1 Week, then select **OK**.
6. Select **SAVE** to complete the item.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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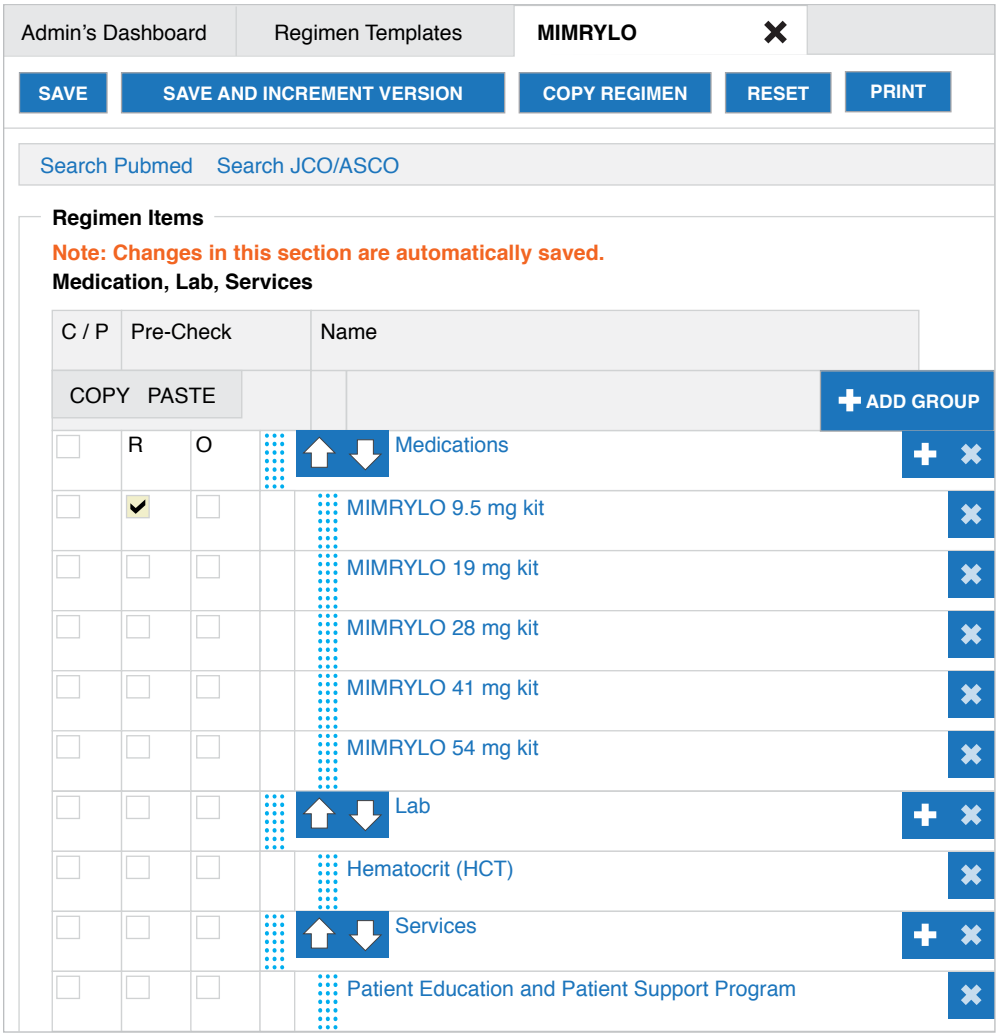
MIMRYLO™ (rusfertide) Regimen (cont.)



Example of updating Regimen items

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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Patient Reports

iKnowMed® patient reports and patient lists provide the ability to accurately identify specific patient populations for clinical, safety, or research purposes.

iKnowMed reports and lists can be used to identify patients with PV who are prescribed MIMRYLO™ (rusfertide) and to support treatment evaluation based on HCT results.

1. Access the **Patient List** widget from the widget Library on the user Dashboard.
2. Select **Create List** to enter search criteria.
3. Select a **Problem** that provides a representative patient population; for example, polycythemia vera.
4. Select any additional criteria to narrow the search, such as current medications, MIMRYLO, and lab results, such as HCT ≥45%.

   Note: *Uncheck Include Any Match to require a match on all criteria.*
5. Select **Search** after appropriate criteria are added.
6. Navigate to each patient's chart directly from the resulting list to review the chart.
7. To save the list from the **Action** dropdown, select **Save As**. Name the list; for example, Patients with polycythemia vera on MIMRYLO with HCT ≥45%.
8. Once the list is created, it can be viewed by selecting the name from the **Patient List** dropdown.
9. To include new patients to the list as time passes, create a Patient List with the same criteria; select an **Action** of **Add To** and select the previously saved list.
10. Select **Save**.

Requesting a Patient List From the EHR IT Support Team

Reports with complex criteria can also be requested from ServiceNow. Inform the iKnowMed Account Manager when requesting a report. Details to include:

Criteria for a patient list that identifies patients with polycythemia vera prescribed MIMRYLO who have an HCT ≥45% and may require treatment evaluation might include:

- Documentation of the diagnosis; for example, D45, polycythemia vera
- Have an active prescription for MIMRYLO
- Have a recent hematocrit (HCT) lab result of ≥45%

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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Mimrylo™ rusfertide for injection

Patient Reports (cont.)

Additional Items to Include in the Request:

- Name for the report, for example, MIMRYLO™ (rusfertide) patients with HCT ≥45%
- Owner of the report, such as a specific healthcare provider or department
- The information to be included in the report output, such as:
  - Medical records number (MRN)
  - Name
  - Age
  - Date of Birth
  - MIMRYLO dose
  - MIMRYLO order date
  - HCT result
  - HCT result date
- Frequency of re-running the report or run on demand

IMPORTANT SAFETY INFORMATION (cont.)

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Alerts

Chart Alerts are notifications within the EHR that prompt consideration of clinical actions, such as ordering tests, evaluating treatment, sending a referral, or scheduling follow-up care. The following steps may be used to configure an Alert that appears at the point of care if the patient has PV, is prescribed MIMRYLO™ (rusfertide), and has a recent HCT result ≥45%.

iKnowMed® enables the setup of Chart Alerts using a Patient List to determine which charts should be reviewed for potential alert notification.

Adding a Chart Alert

1. Navigate to the **Patient List Search**, select the save report; for example, Patients with PV prescribed MIMRYLO with HCT ≥45%.
2. From the resulting **Patient List Search**, navigate to each patient chart and review the chart for inclusion and exclusion data points.
3. If an alert is appropriate, navigate to **Clinical Profile**, **Chart Alerts**, **ADD ALERT….**
4. Select the Alert Type **Clinical Alert** and appropriate options, such as **Display when Chart is Opened** and **Display** on dashboard **Visit Type**.
5. Enter Alert Details, such as patient has a recent HCT ≥45% and is on MIMRYLO. Review clinical data for potential dose adjustment.
6. Select **Save**.

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EHR Worksheets

Report Criteria

This criteria supports identifying patients with PV on MIMRYLO™ (rusfertide) therapy who may require dose adjustment.

Inclusion Criteria

Category	✔	Values
Patient Status	☐	Alive
Patient Population	☐	Only my patients
	☐	Seen in my department
	☐	All patients who meet the criteria
	☐	Other
Patient Gender	☐	Female
	☐	Male
	☐	Not specified
Race/Ethnicity	☐	White
	☐	Black or African American
	☐	American Indian or Alaska Native
	☐	Asian
	☐	Native Hawaiian or other Pacific Islander
	☐	Not specified
Age	☐	Custom range -

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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EHR Worksheets (cont.)

Inclusion Criteria (cont.)

Category	✔	Description	Code Set	Code	Result
Diagnosis	☐	Polycythemia vera	ICD-10	D45	
Lab Result	☐	Hematocrit	CPT	85014, 85025	≥ 45%
Medication	☐	MIMRYLO™ (rusfertide)			
	☐	BESREMi® (ropeginterferon-alfa-2b-njft)			
	☐	Jakafi® (ruxolitinib)			
	☐	Jakafi XR™ (ruxolitinib)			
	☐	Hydrea (hydroxyurea)			
Procedure	☐	Therapeutic phlebotomy	CPT	99195	
	Timeframe for capturing and/or Value (e.g., within the last 6 months is [m-6])			Lookback period (starting today):	

Exclusion Criteria

Category	✔	Description	Code Set	Code	Status
	☐	Other			
	Timeframe for capturing and/or Value (e.g., within the last 6 months is [m-6])			Lookback period (starting today):	

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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EHR Worksheets (cont.)

Report Output

Report Output	✔	Description	Code Set	Code
Patient Demographics	☐	Name		
	☐	MRN		
	☐	DOB		
Diagnosis	☐			
Medication	☐			
Procedures	☐	Therapeutic phlebotomy date		
Lab Result	☐	Hematocrit and date of last result		

IMPORTANT SAFETY INFORMATION (cont.)

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EHR Worksheets (cont.)

Alert Criteria

Category	✔	Values
Alert Name Patients with polycythemia vera prescribed MIMRYLO™ (rusfertide) with HCT ≥45%	☐	
Message to Include in Alert Patient has a recent HCT ≥45% and is on MIMRYLO. Review clinical data for potential dose adjustment.	☐	
Clinical Data to Display on Alert	☐	Polycythemia Vera D45
	☐	
Alert Trigger Criteria	☐	Opening of patient chart
	☐	
Frequency of Alert	☐	Once per encounter
	☐	Once per encounter per user
	☐	Multiple times per event within the encounter
	☐	
Display Restrictions	☐	Care team member
	☐	Physician
	☐	Department
	☐	Other

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.

Please see additional Important Safety Information throughout and on page 21. Please see MIMRYLO (rusfertide) full Prescribing Information.

EHR Worksheets (cont.)

Alert Criteria (cont.)

Category	✔	Values	
Clinical Actions to Take Based on the Alert	☐	Open PV Regimen _____ Order Set # _____	
	☐	Order MIMRYLO™ (rusfertide) _____	
	☐	Open Hematology Synopsis View	
	☐	Other _____	
Acknowledge Reason(s)	☐	Patient refused	Lockout Period _____
	☐	Continue to monitor	Lockout Period _____
	☐	Other _____	Lockout Period _____
	☐	_____	Lockout Period _____

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

- **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.

Please see additional Important Safety Information throughout and on page 21. Please see MIMRYLO (rusfertide) full Prescribing Information.

Important Safety Information and Indication

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 MIMRYLO (rusfertide) full Prescribing Information.

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