Mimrylo™ rusfertide for injection

Leveraging OncoEMR® 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 19. 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.

The information listed in this resource is based upon the most recent version of OncoEMR®; functions and features may change as new software versions are released. 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 OncoEMR. 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 appropriate workflows.

The instructions listed in this guide are for use with the most current version of OncoEMR 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 OncoEMR.

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**
  - **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.

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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.)

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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.)

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.
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MIMRYLO™ (rusfertide) Regimen

Upon request and approval from the clinical team, the EHR IT Support Team creates regimens that include the necessary orders for a given course of treatment. When there are existing regimens, it may be easier to edit and adapt what is already in the EHR. However, a new regimen can also be created if needed.

When a healthcare professional assigns a regimen to a patient, it becomes the patient's plan for treatment. Once the healthcare professional has created a regimen specific to the patient, OncoEMR® enables users to save it as a preferred regimen. Regimens can be saved in a healthcare professional's individual library—and can optionally be shared publicly with others in the practice or in the entire health system.

Note: *Users can create new regimens; however, creating or editing custom regimen templates requires full permissions.*

Creating a Regimen for MIMRYLO

Regimens facilitate care by organizing clinical actions for the administration and monitoring of infusion medications across multiple encounters within a defined time frame. If a Regimen does not already exist, a new Regimen can be created and populated with the appropriate clinical components to support consistent and streamlined care delivery. Alternatively, users may create a new Regimen by copying an existing template and updating it as needed.

1. Navigate to the **Customize** page and choose **Regimen List**.
2. Select **New Regimen** to display a blank template.
3. Enter a name for the Regimen, according to the practice conventions; for example, MIMRYLO.
4. In the **Description** field, select **Edit**, then select the **Global/Link** icon to add reference links for provider information.
5. In the **Important Safety Information** field, select **Edit** to include MIMRYLO's indication information.

   Note: *For example, indication information may include: MIMRYLO is a peptide mimetic of hepcidin indicated for the treatment of adults with polycythemia vera.*
6. Enter **Associated Disease(s)**; for example, Polycythemia Vera.
7. Set **Cycle Lengths and Counts**; for example, 7 Days.
8. Select **Update Calendar**.

IMPORTANT SAFETY INFORMATION

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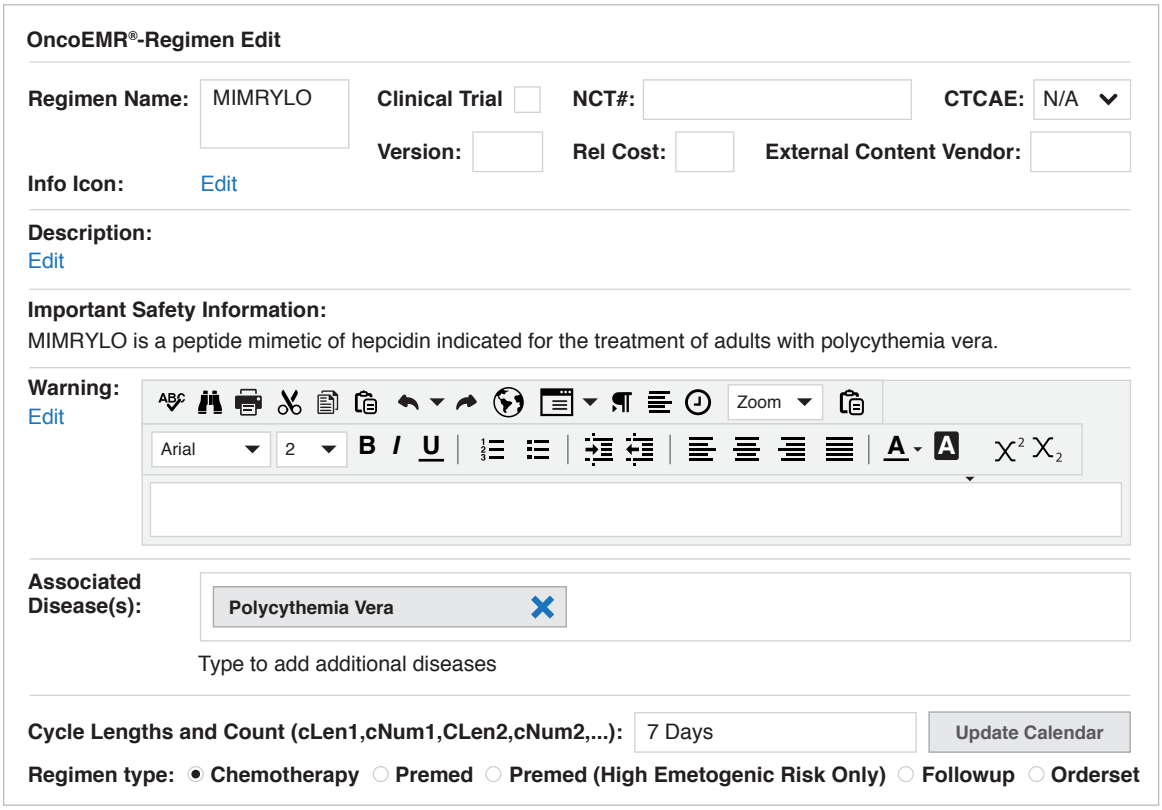
MIMRYLO™ (rusfertide) Regimen (cont.)



Example of the Regimen Edit options

9. In the **Calendar**, add orders to the Regimen. From the **Add** options, select **Drug**.
10. Search for and select MIMRYLO (rusfertide) 19 mg to add to the Regimen.
11. In the Regimen build sheet, set appropriate days for the injections to be ordered; for example, **once weekly**. Refer to the MIMRYLO PI Link for dosing information and Takeda Oncology Here2Assist here2assist.com or through www.mimrylo.com for the digital enrollment platform and for prescription routing.

    Example dose information:

    a. **Dose:** 19 mg

    b. **Subsequent dosing:** Patient administering subcutaneously

    c. **Frequency:** Once weekly

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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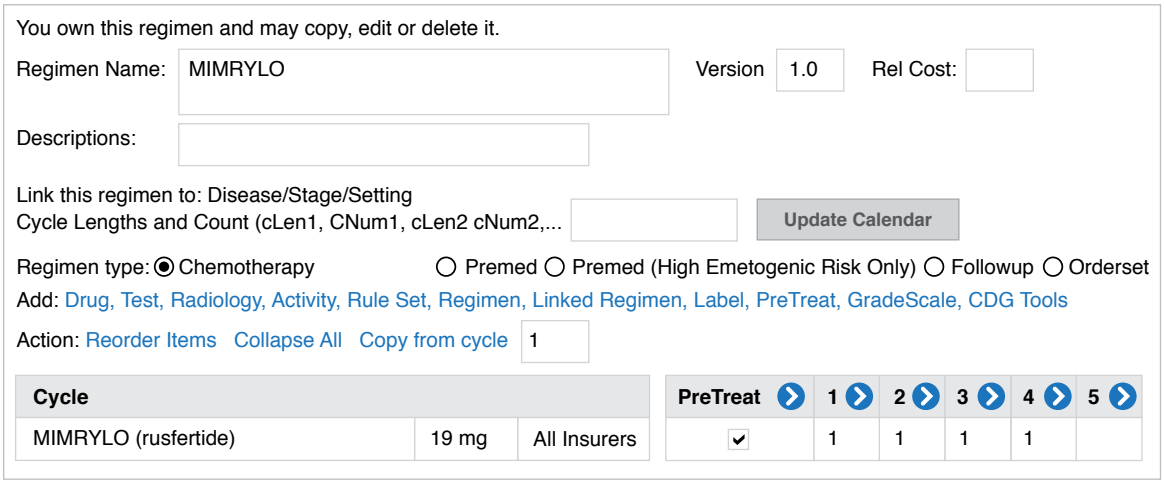
MIMRYLO™ (rusfertide) Regimen (cont.)


You own this regimen and may copy, edit or delete it.

Regimen Name: MIMRYLO Version 1.0 Rel Cost:

Descriptions:

Link this regimen to: Disease/Stage/Setting
Cycle Lengths and Count (cLen1, CNum1, cLen2 cNum2,... Update Calendar

Regimen type: ◉ Chemotherapy ○ Premed ○ Premed (High Emetogenic Risk Only) ○ Followup ○ Orderset

Add: Drug, Test, Radiology, Activity, Rule Set, Regimen, Linked Regimen, Label, PreTreat, GradeScale, CDG Tools

Action: Reorder Items Collapse All Copy from cycle 1

Cycle			PreTreat	1	2	3	4	5
MIMRYLO (rusfertide)	19 mg	All Insurers	☑	1	1	1	1	

Example of MIMRYLO added to the Regimen

12. From the **Add** options, select **Test**. Search for and select **Hematocrit tests**.
13. In the **Calendar** view, set appropriate days for the injections to be ordered; for example, once weekly.
14. Select **Save**.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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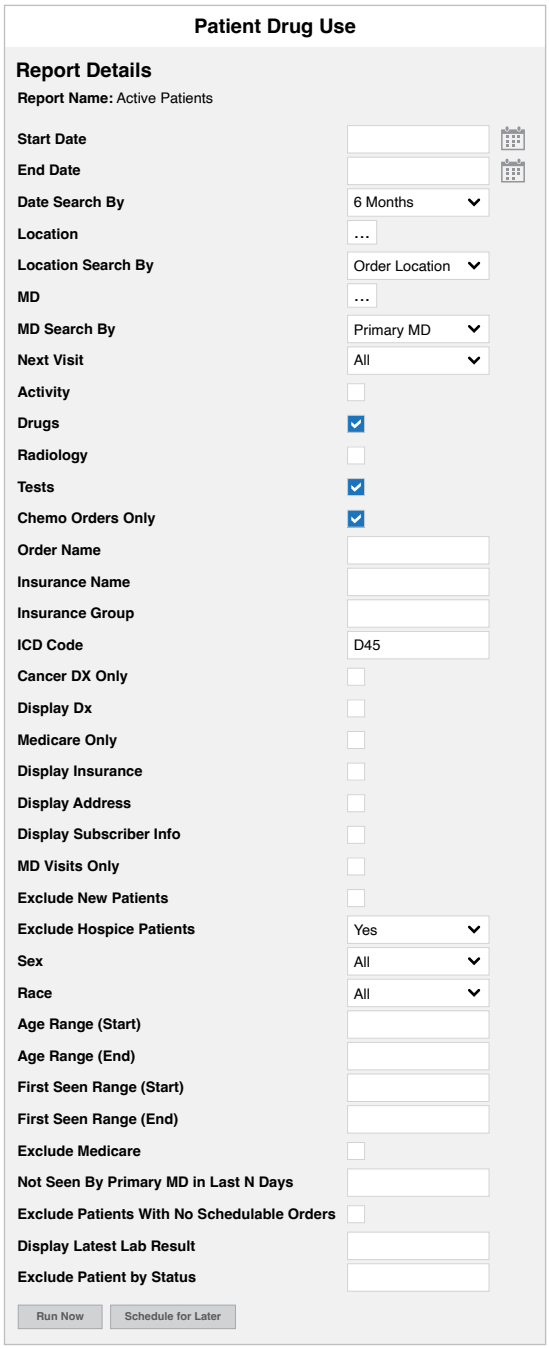
Patient Reports

Developing Patient Reports

OncoEMR® standard reports provide the ability to accurately isolate specific segments of a patient population for clinical, safety, or research purposes. In support of MIMRYLO™ (rusfertide), these reports may be used to identify patients with PV who are prescribed MIMRYLO and may benefit from therapy adjustment based on HCT results.

1. Navigate to **Reports** and select the **Active Patients** report.
2. Select **Start** and **End Dates**, **Location**, and other specific criteria as desired.
3. Select the diagnosis codes that provide a representative group of the PV patient population; for example, D45.
4. Select any additional applicable criteria options, such as Medication (MIMRYLO), Labs (HCT), Age, and Next Visit.
5. Select **Run Now** or **Schedule for Later.**



Example of a patient report

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS

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

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Patient Reports (cont.)

Requesting Patient Reports From the EHR IT Support Team

A patient report can also be created by the EHR IT Support Team and made available for on-demand running or scheduling by the requester.

In the case of complex criteria, the healthcare professional making the request must provide key information for the report before the setup can be managed by the EHR IT Support Team. This is usually part of a typical process for requesting, approving, and implementing EHR changes.

What to request:

- Criteria—polycythemia vera
- Name of the report, such as Patients with polycythemia vera prescribed MIMRYLO™ (rusfertide)
- Owner of the report, such as a specific healthcare professional or department
- The information to be included in the report output, such as name, MRN, date of birth, diagnosis, HCT last result and last test date, MIMRYLO dose, and last ordered

Use the EHR Worksheets to gather the necessary information to include in the EHR IT Support Team request.

IMPORTANT SAFETY INFORMATION (cont.)

USE IN SPECIFIC POPULATIONS

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Alerts

Using Alerts to Prompt Treatment Evaluation

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 for patients with PV who are prescribed MIMRYLO™ (rusfertide) with recent HCT result of ≥45%.

1. Navigate to the patient chart. Select **Demographics**.
2. In the **Miscellaneous Data** section, select **New**.
3. In the **Edit/Enter Misc Patient Information** window, **Item Name** field, enter **showonpatientpopup**. In the **Value** field, add the message to be displayed in the pop-up when the chart is accessed; for example, Patient's HCT remains ≥45% and may benefit from therapy adjustment.
4. Select **Save**.
5. When the chart is opened, the defined pop-up alert displays.

Requesting Alerts From the EHR IT Support Team

Additional detailed, specific chart alerts based on clinical criteria can be requested from OncoEMR® support. Once built, the Alert will display based on chart data in a manner similar to clinical decision support alerts.

The following are examples of information to request for an automated clinical alert to the provider when a patient with PV is prescribed MIMRYLO and has a recent HCT ≥45%.

What to request:

- Criteria—patients diagnosed with polycythemia vera, prescribed MIMRYLO, recent HCT ≥45%
- Title for the Alert, such as Patients with polycythemia vera, prescribed MIMRYLO, HCT ≥45%
- Message for the Alert; for example, Patient's hematocrit remains ≥45% and may benefit from therapy adjustment.
- When to display the Alert; for example, physician level only, upon chart open, etc.

Use the EHR Worksheets to gather the necessary information to include in the EHR IT Support Team request.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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Patient Education

Patient Education Orders help bridge the gap between what healthcare professionals intend and what patients understand and do. Adding patient education and/or patient information orders to relevant regimens lets care teams know the content is available and can be provided to appropriate patients. In this guide, patient education and patient information are referred to in the singular term of "patient education." Note that patient education is part of the formulary item; it is available and customizable. Once added to the formulary item, patient education can be added to the appropriate regimen.

1. To add patient education to the formulary item, navigate to the Information icon and select **Edit custom patient education**.
2. Add desired patient education, including patient support resource information.
3. Select **Save**.
4. Navigate to the **Customize** page and choose **Regimen List**. Search for the appropriate Regimen, such as MIMRYLO™ (rusfertide).
5. When edits are completed, navigate to the **Select an Action** dropdown, choose **Move (promote) to PRACTICE**.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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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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Mimrylo™ rusfertide for injection

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.)

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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

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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 lab results	
	☐	Other _____	
Acknowledge Reason(s)	☐	Patient refused	Lockout Period _____
	☐	Continue to monitor	Lockout Period _____
	☐	Other _____	Lockout Period _____
	☐	_____	Lockout Period _____

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WARNINGS AND PRECAUTIONS (cont.)

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Important Safety Information and Indication

INDICATION

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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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