Mimrylo™
rusfertide for injection

Leveraging Epic® 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 46. 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 Epic®; 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 Epic. 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 Epic 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 Epic.

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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WARNINGS AND PRECAUTIONS

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Mimrylo™ rusfertide for injection

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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Mimrylo™ rusfertide for injection

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

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

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Mimrylo™ rusfertide for injection

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:

- SmartSets
- 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.
- **Females and Males of Reproductive Potential**
  - **Pregnancy Testing:** Prior to initiating MIMRYLO, pregnancy testing is recommended for females of reproductive potential.
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MIMRYLO™ (rusfertide) SmartSet

SmartSets are a set of orderable and actionable items that include orderable items. SmartSets include SmartGroups, which can be used in multiple SmartSets for consistency across an organization. A SmartGroup organizes specific and related clinical items typically used together (e.g., orders, medications, or tasks) so that they can be easily managed and reused across the EHR. Once created, SmartGroups can be embedded into multiple different SmartSets or Order Sets to enable standard and consistent care without requiring the prescriber to search for what they need.

While a SmartGroup is a small set of orders, a SmartSet encompasses all necessary components for a specific diagnosis, procedure, or patient encounter in a single screen—including SmartGroups and documentation tools.

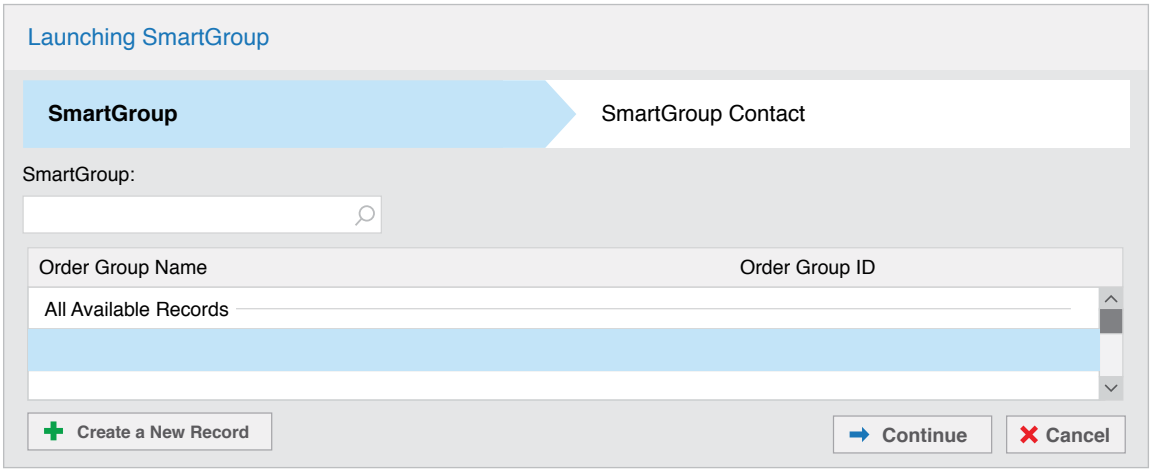
The following steps provide an overview of the processes for:

- Creating orderable items for multiple prescriptions
- Adding medications, lab orders, or patient education to a SmartGroup

Creating a SmartGroup for an Orderable Dose With Multiple Drug Strengths

Ordering a drug dose that is comprised of multiple drug strengths can require multiple prescriptions; creating a SmartGroup can facilitate the process.

1. Search for and select **SmartGroups** [OSQ].
2. In the Launching SmartGroup window, select **+ Create New Record**.



Example of initial New Record launch

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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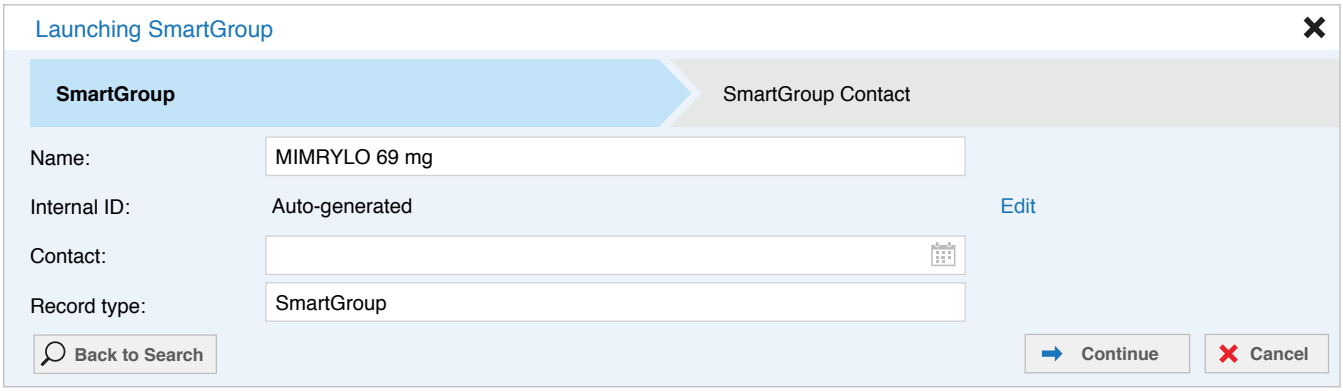
MIMRYLO™ (rusfertide) SmartSet (cont.)

3. Enter an appropriate **Name** for the SmartGroup; for example, MIMRYLO 69 mg.

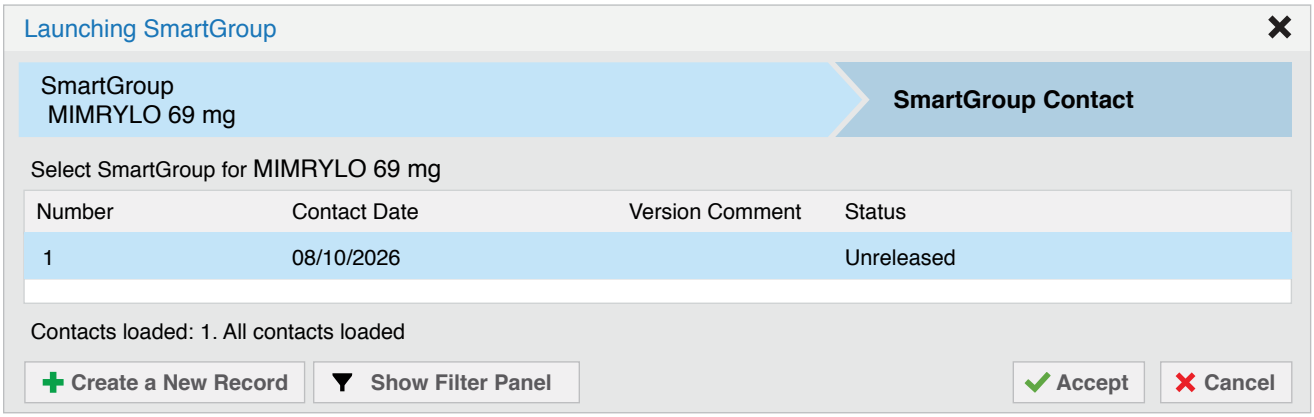
   Note: *The Internal ID is auto-generated and the date will default to the current date.*

4. Select **Continue**.



Example of creating new SmartGroup

5. To add orders to the new SmartGroup, select **Accept**.



Example of SmartGroup contact

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.

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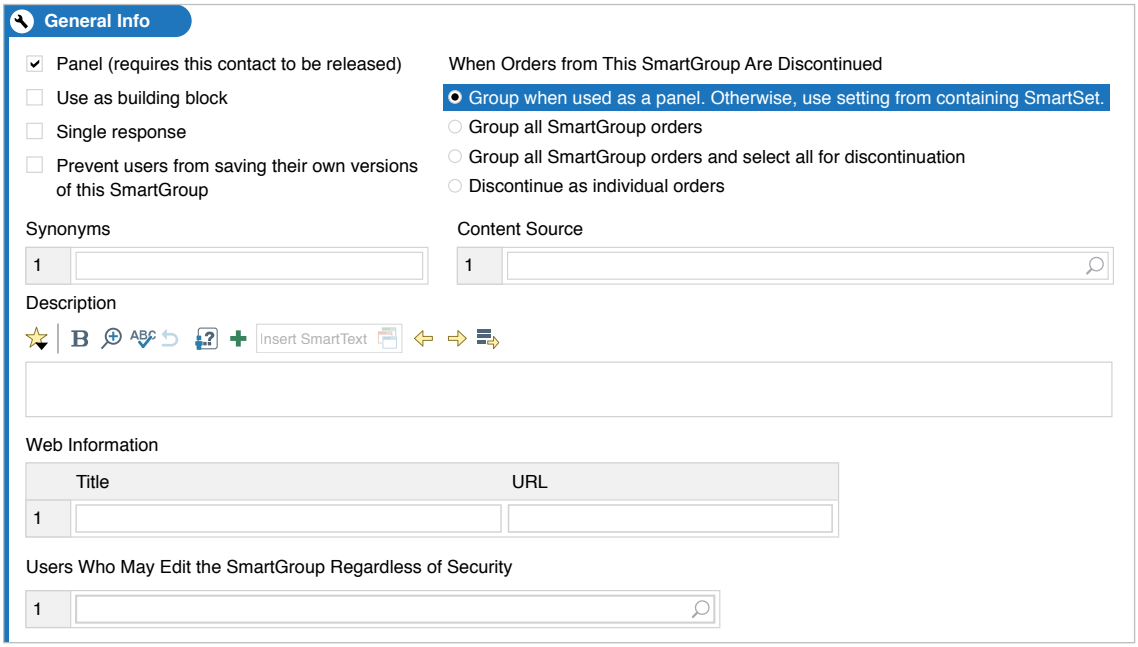
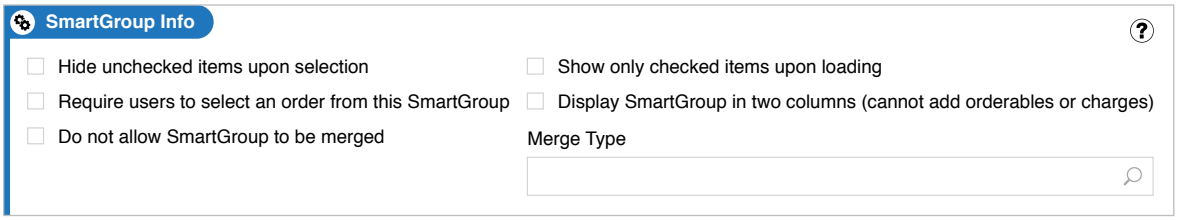
MIMRYLO™ (rusfertide) SmartSet (cont.)

6. In the **About** section, update any information needed, such as **Version Comment** or **Change Comment**.
7. In the **General Info** section, select the checkbox **Panel (requires this contact to be released)**.



Example of Panel selection within the General Info template

8. In the **SmartGroup Info** section, uncheck **Show only checked items upon loading**.



Example of checkbox selection within the SmartGroup Info template

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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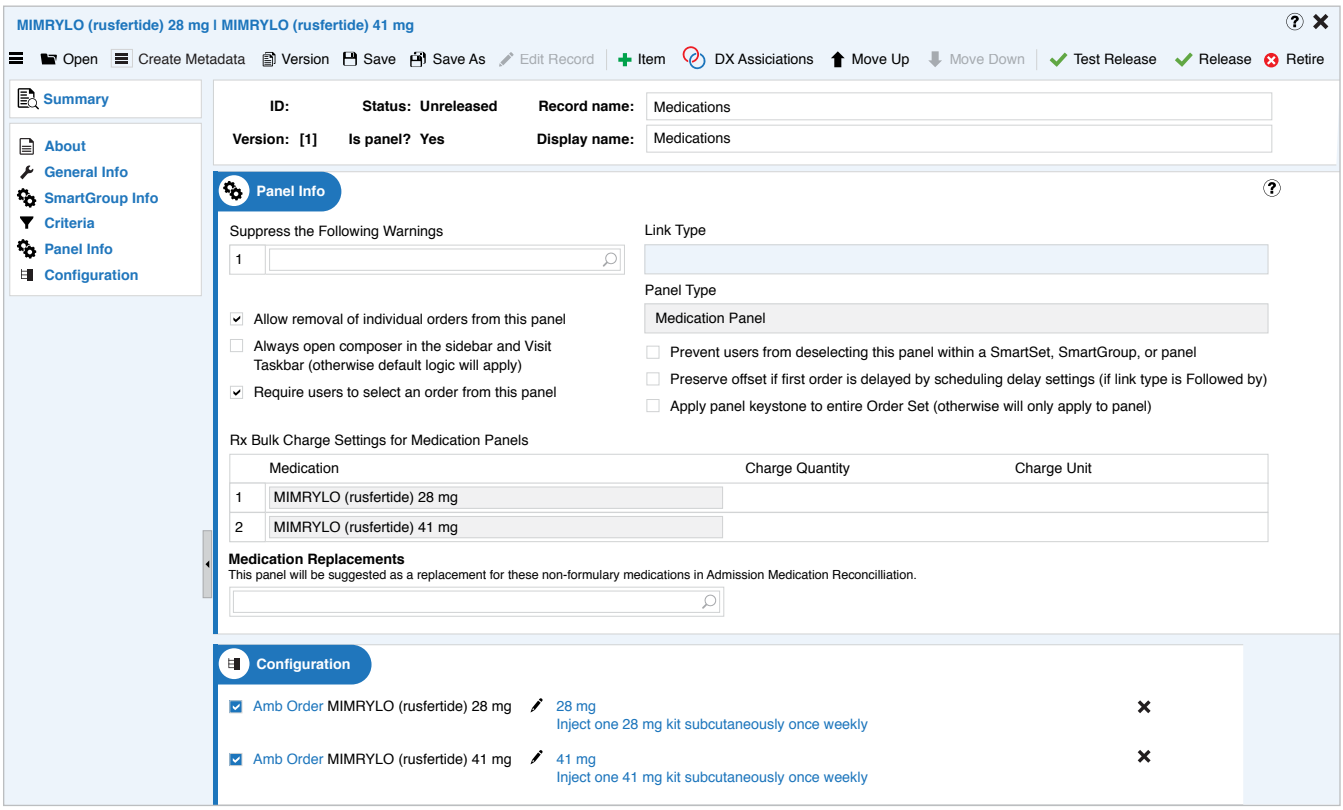
MIMRYLO™ (rusfertide) SmartSet (cont.)

9. In the **Panel Info** section, set **Panel Type** to **Medication Panel**. Leave all other defaults as is.



Example of Panel Type selection within the Panel Info template

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS

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

USE IN SPECIFIC POPULATIONS

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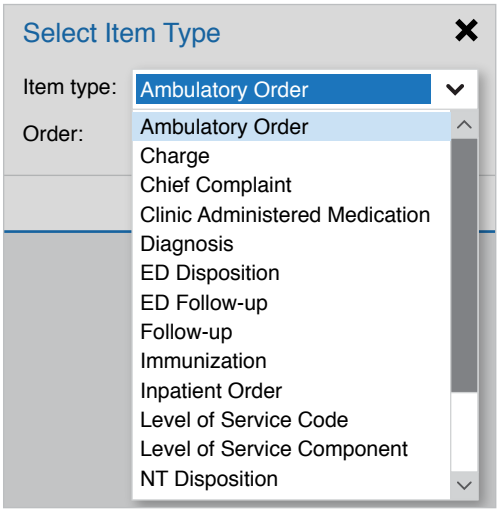
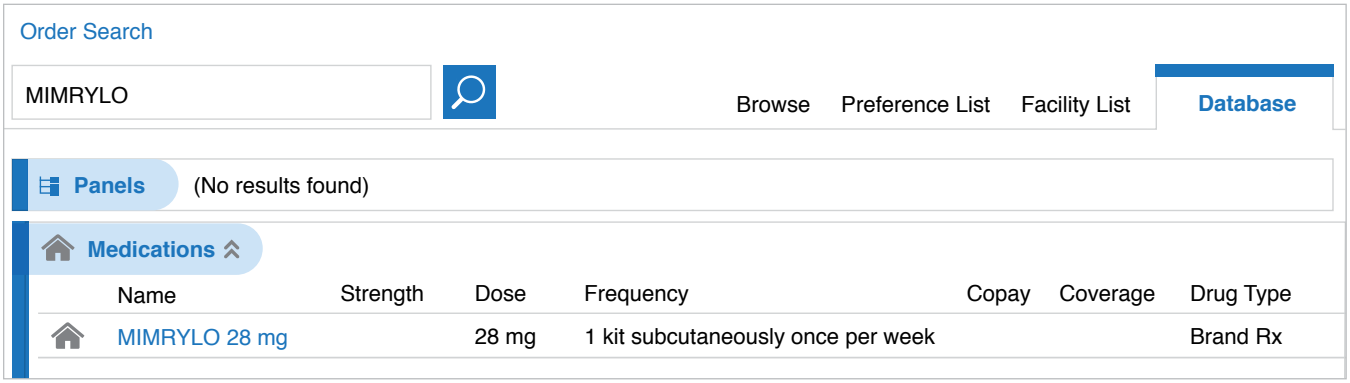
MIMRYLO™ (rusfertide) SmartSet (cont.)

10. Select **Add Item** from the toolbar.
11. In **Select Item Type**, use the dropdown to select the appropriate **Item type**; for example, **Ambulatory Order**.



Example of setting context for Order

12. Search for the appropriate Order to add; for example, MIMRYLO 28 mg.
13. Select **Accept**.



Example of adding new Order

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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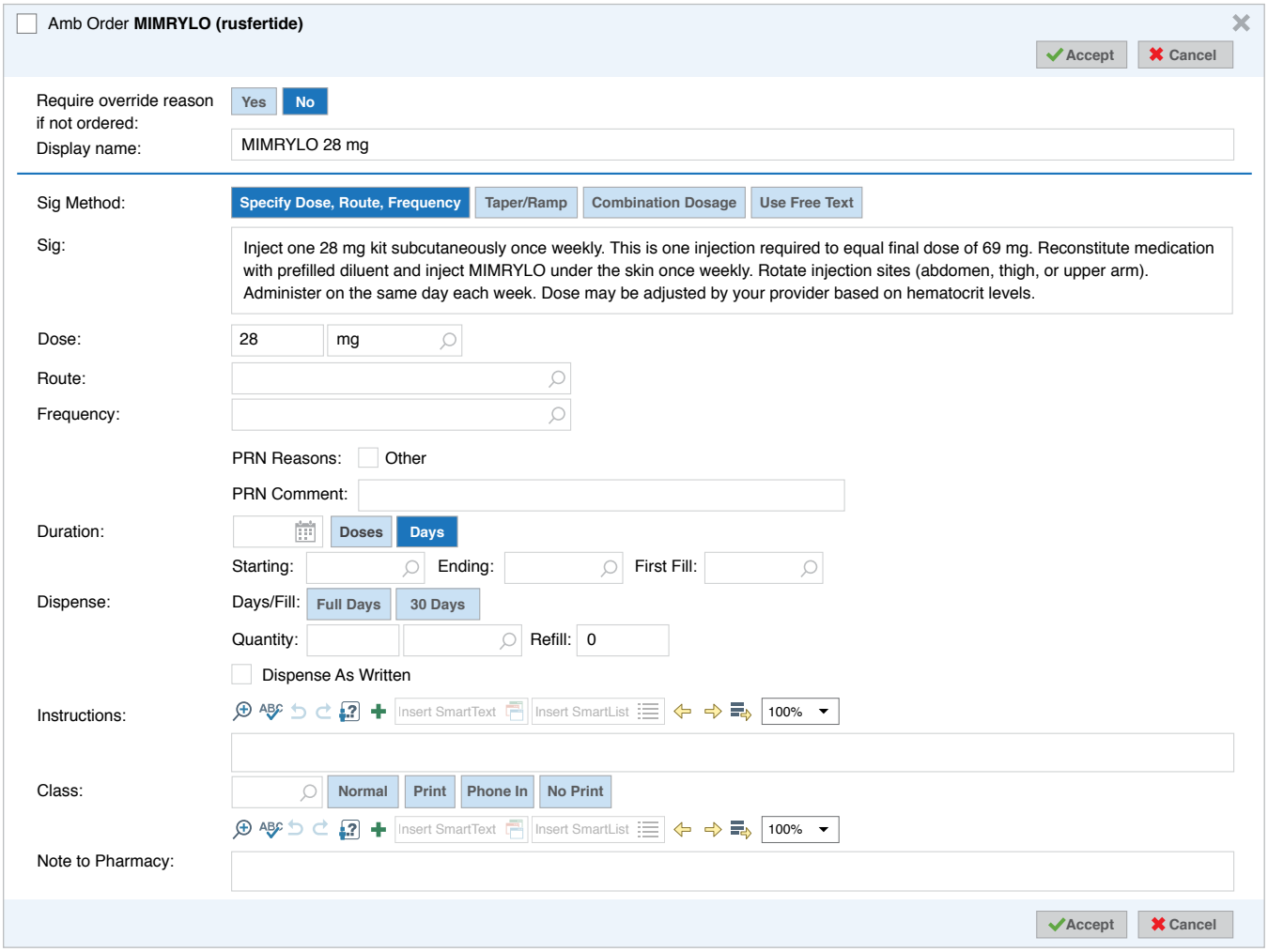
MIMRYLO™ (rusfertide) SmartSet (cont.)

14. Once the Order has been added, users can then set appropriate details; for example, **Display name**, **Sig**, **Dose**, and **Route**.



Example of MIMRYLO 28 mg Order details

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.

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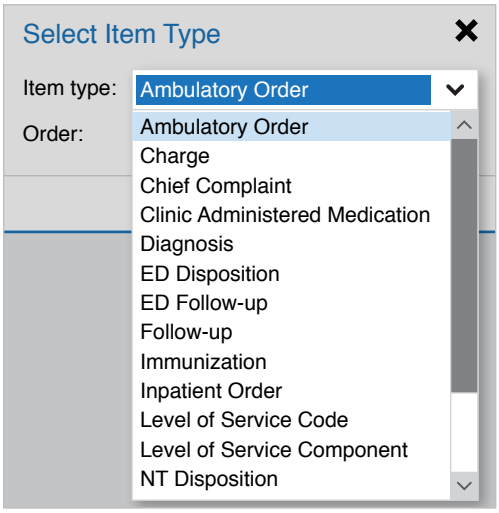
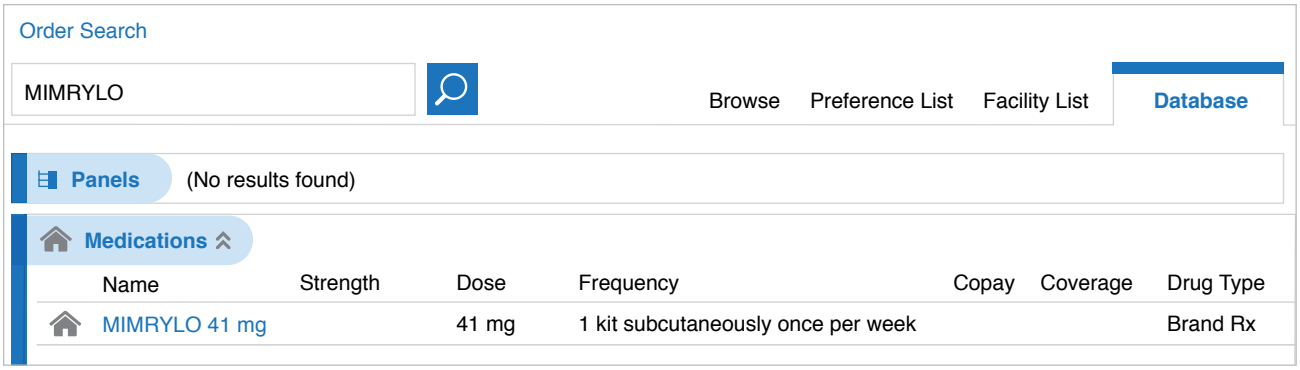
MIMRYLO™ (rusfertide) SmartSet (cont.)

15. Select **Accept**.
16. Select **Add Item** from the toolbar.
17. In **Select Item Type**, use the dropdown to select the appropriate **Item type**; for example, **Ambulatory Order**.



Example of setting context for Order

18. Search for the appropriate **Order** to add; for example, Rusfertide 41 mg.
19. Select **Accept**.



Example of adding new Order

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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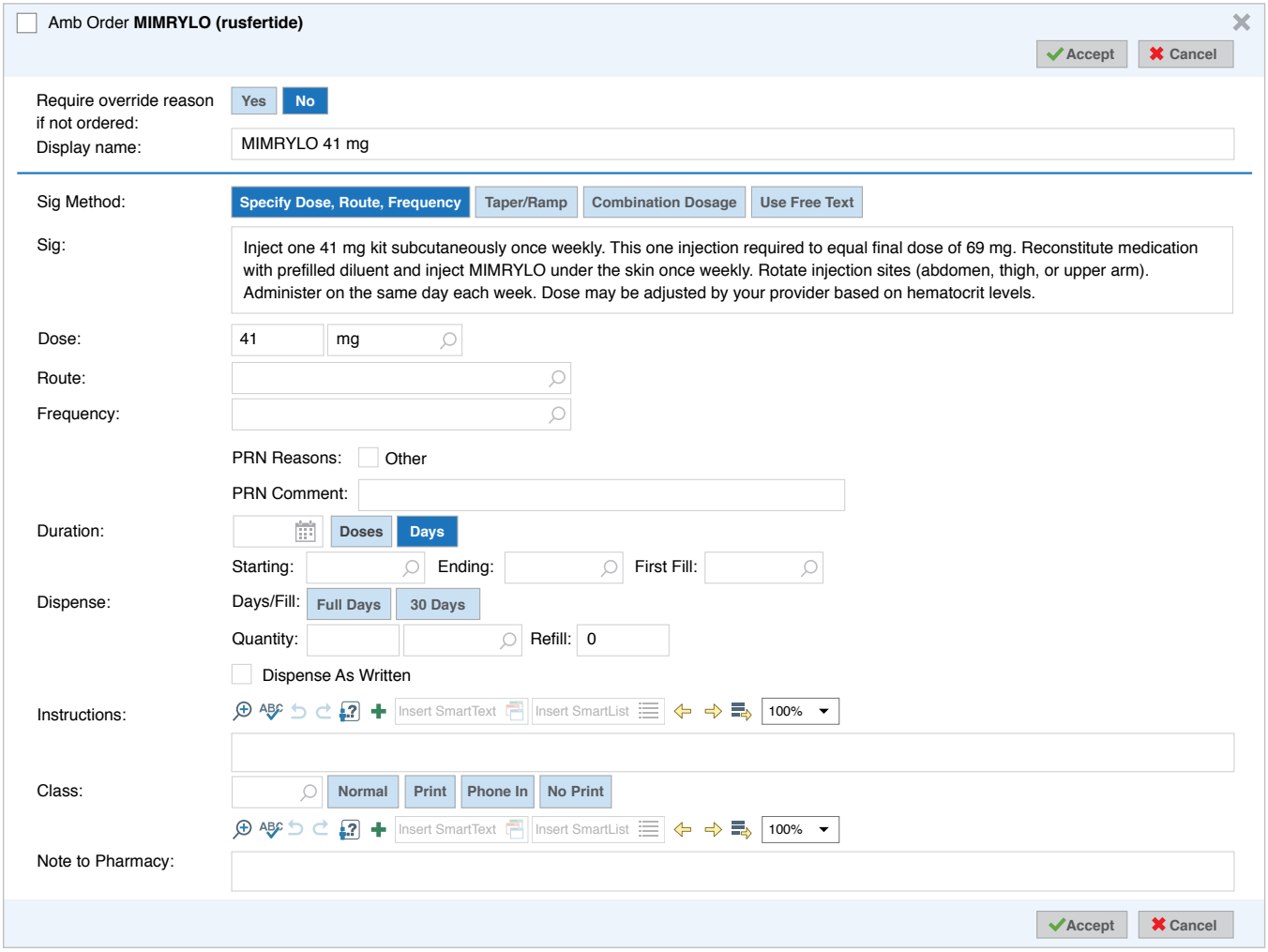
MIMRYLO™ (rusfertide) SmartSet (cont.)

20. Once the Order has been added, users can then set appropriate details; for example, **Display name**, **Sig**, **Dose**, and **Route**.
21. Select **Accept.**



Example of MIMRYLO 41 mg Order details

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS

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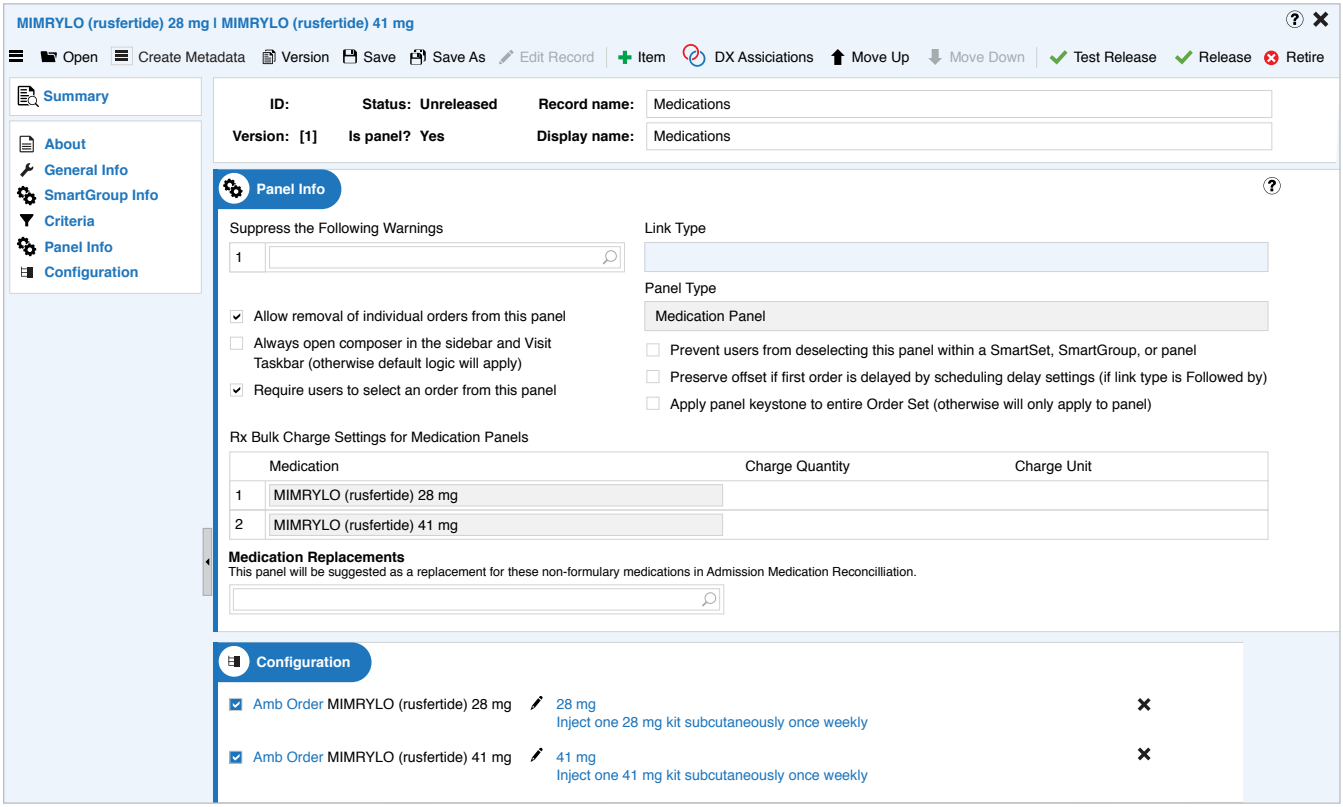
MIMRYLO™ (rusfertide) SmartSet (cont.)

22. Once build is complete, select **Release** for use by all users in the organization.

Note: *When a provider picks MIMRYLO 69 mg, both doses will be preselected for them with details for patient and pharm.*



Example of Release buttons in toolbar

23. Repeat steps above for the 95 mg dose.

Note: *Order panels can be added to desired Medication SmartGroups just as they would any other standard order.*

IMPORTANT SAFETY INFORMATION (cont.)

USE IN SPECIFIC POPULATIONS

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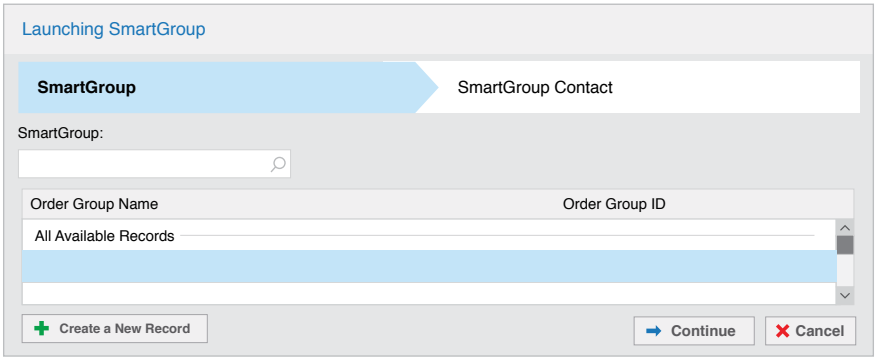
MIMRYLO™ (rusfertide) SmartSet (cont.)

Adding a SmartGroup for Medications

Adding medications to a SmartGroup supports consistent and efficient ordering at the point of care and during follow-up visits to reduce variation and reinforce alignment with established treatment pathways.

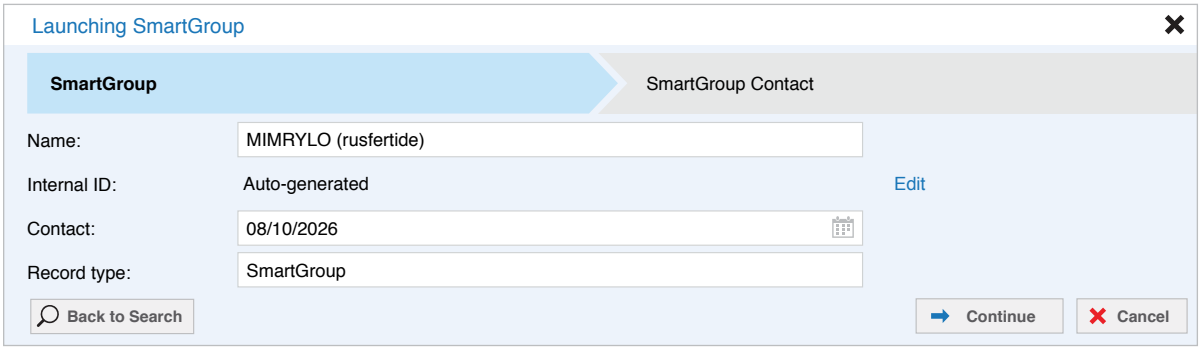
1. Search for and select **SmartGroups** [OSQ].
2. In the **Launching SmartGroup** window, select **+ Create a New Record**.



Example of initial creation of New Record launch Medications

3. Enter an appropriate **Name** for the SmartGroup; for example, use **Medications**.

   Note: *The Internal ID is auto-generated, and the date will default to the current date.*
4. Select **Continue**.
5. To add orders to the new SmartGroup, select **Continue**, then select **Accept**.



Example of a SmartGroup MIMRYLO for Medications, Named MIMRYLO (rusfertide)

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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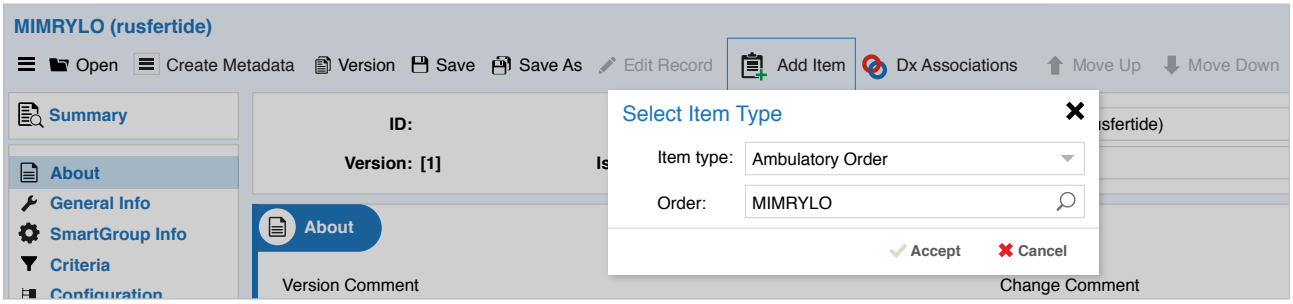
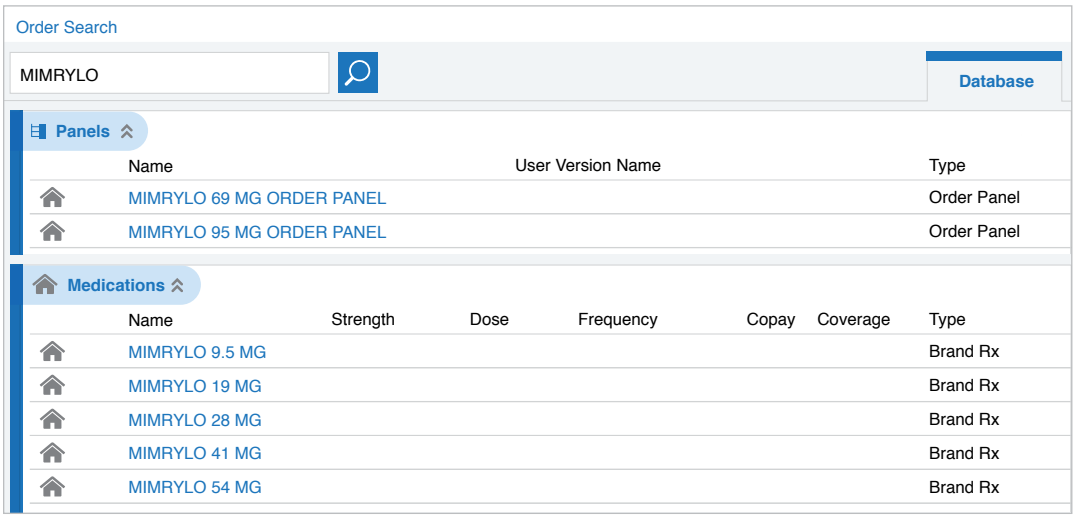
MIMRYLO™ (rusfertide) SmartSet (cont.)

6. Select **Add Item** from the toolbar.
7. In **Select Item Type**, use the dropdown to select the appropriate **Item type**; for example, choose **Ambulatory Order**.
8. Search for the appropriate **Order** to add; for example, use MIMRYLO, then select **Accept**.



Example of adding Item Type for medication SmartGroup



Example of adding a new order for MIMRYLO SmartGroup

9. Once the Order has been added, set appropriate details; for example, **Record name**, **Display name**, **Dose**, **Route**, and **Frequency**.
10. Select **Accept**.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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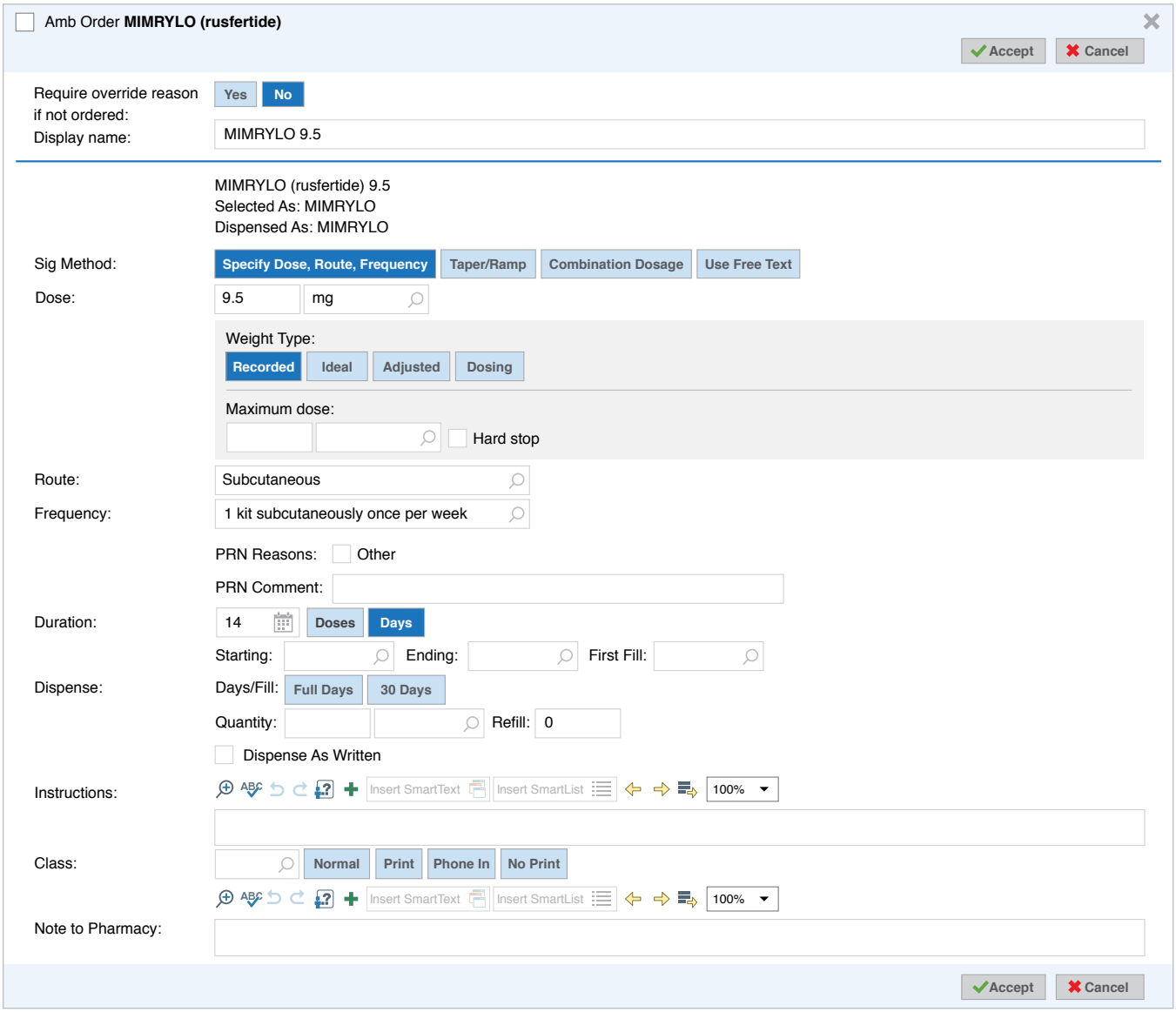
Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

MIMRYLO™ (rusfertide) SmartSet (cont.)



Example of MIMRYLO Order details

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.

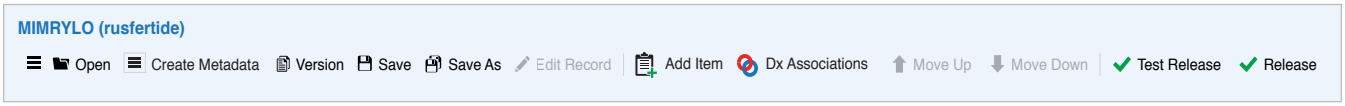
Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

MIMRYLO™ (rusfertide) SmartSet (cont.)

11. When all appropriate **Orders** have been added to this SmartGroup, select **Test Release** to test the SmartGroup.

    Note: *The Test Release version is only visible to the health system IT team; end users cannot see the SmartGroup at this stage.*

12. Once testing is complete, select **Release** for use by all users in the organization.



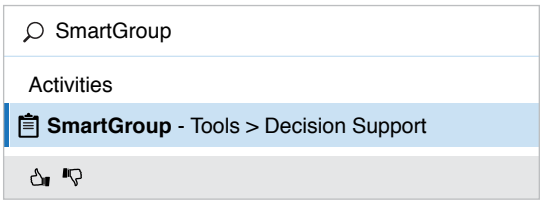
Example of Release buttons in the toolbar for releasing the standing Medications SmartGroup

Adding a SmartGroup for Labs

Adding laboratory orders to a SmartGroup supports consistent diagnostic evaluation at the point of care and throughout ongoing care. Standardizing lab selections may helps ensure appropriate monitoring, reduce omissions, and support longitudinal clinical decision-making.

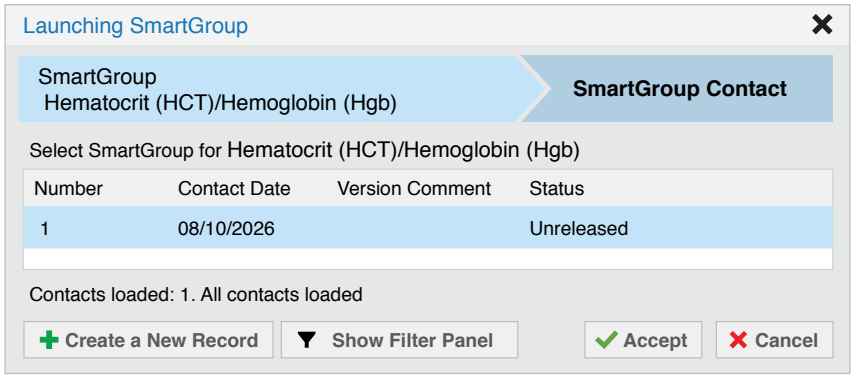
1. Search for and select **SmartGroups** [OSQ].
2. Select **+ Create a New Record** and enter the desired name, such as MIMRYLO Labs and follow suit in the images.
3. Select **Continue**.

   Note: *The Internal ID is auto-generated and the date will default to the current date.*



Example of SmartGroup search

4. Select **Accept**.
5. Select the **Configuration** form.
6. Select **Add Item**.
7. Add **Item Type** and **Order**.
   a. **Item Type:** Ambulatory Order
   b. **Order:** Hematocrit (HCT)/Hemoglobin (Hgb)
   c. Select **Accept**.



Example of Creating a Hematocrit (HCT)/Hemoglobin (Hgb) SmartGroup

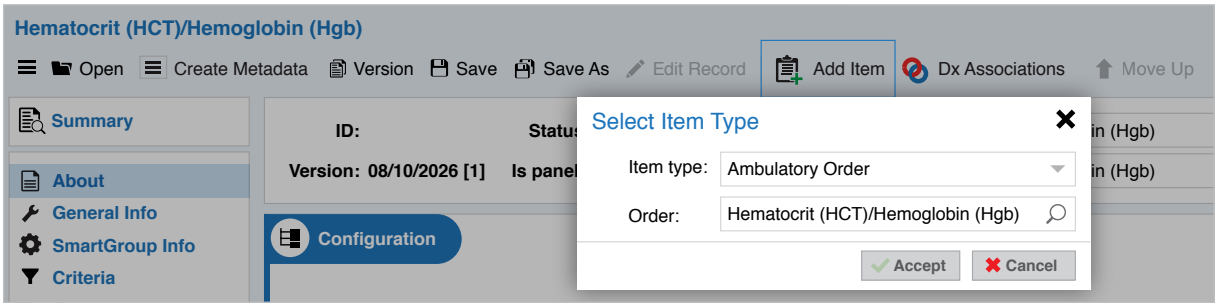
IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS

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

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

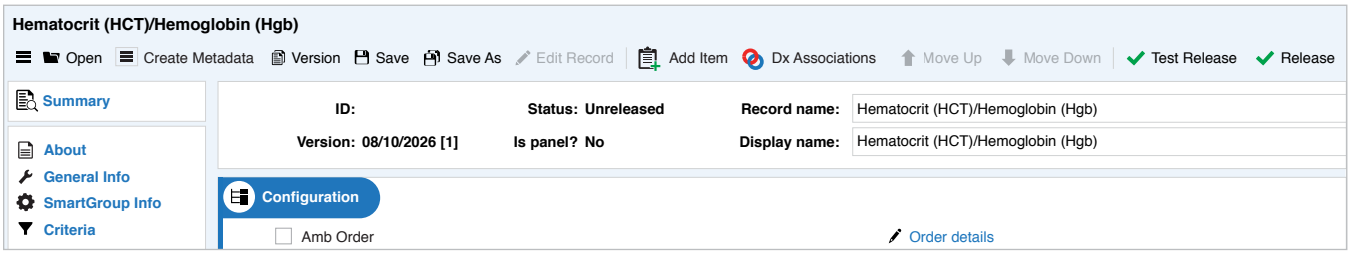
MIMRYLO™ (rusfertide) SmartSet (cont.)



Example of Smartgroup Configuration Form

8. Add any order defaults as appropriate.
9. Select **Accept**.
10. When all orders have been added, select **Release**.

    Note: *SmartGroups can default to show all items as preselected, and unwanted items must be unchecked. They can also default to show no items selected, and each desired item must be manually checked to be ordered. If items are always ordered together, it is recommended to choose the preselected default.*



Example of Releasing Orders

11. When complete, add this to the SmartSet.

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.
- **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.

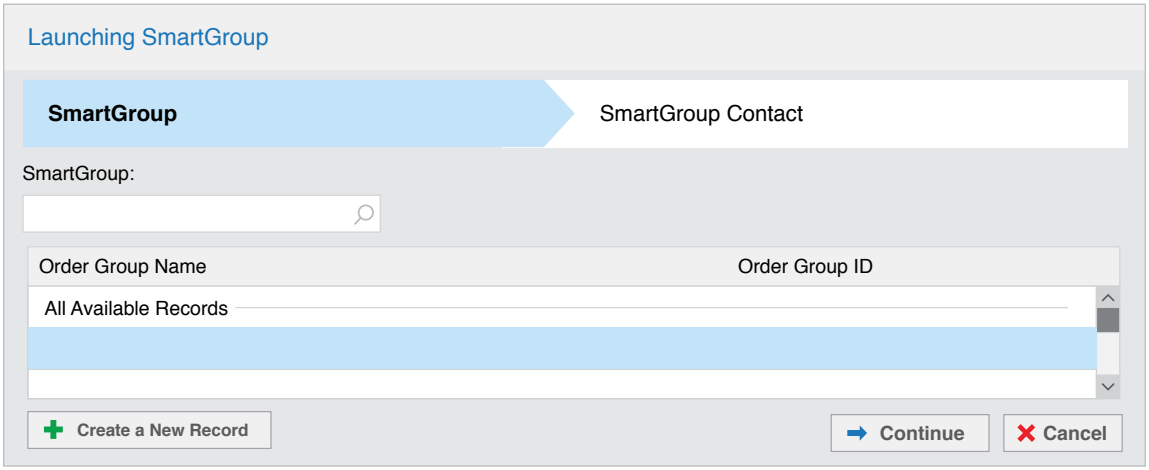
Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

MIMRYLO™ (rusfertide) SmartSet (cont.)

Adding a SmartGroup for Patient Education

With a new SmartSet, both new and existing SmartGroups can be included, supporting efficiency by leveraging existing, validated content while maintaining consistency across workflows.

1. Search for and select **SmartGroup** [OSQ].
2. In the **Launching SmartGroup** window, select **+ Create a New Record**.



Example of initial New Record launch

3. Enter an appropriate **Name** for the SmartGroup; for example, use **Patient Education**.

   Note: *The Internal ID is auto-generated, and the date will default to the current date.*

IMPORTANT SAFETY INFORMATION

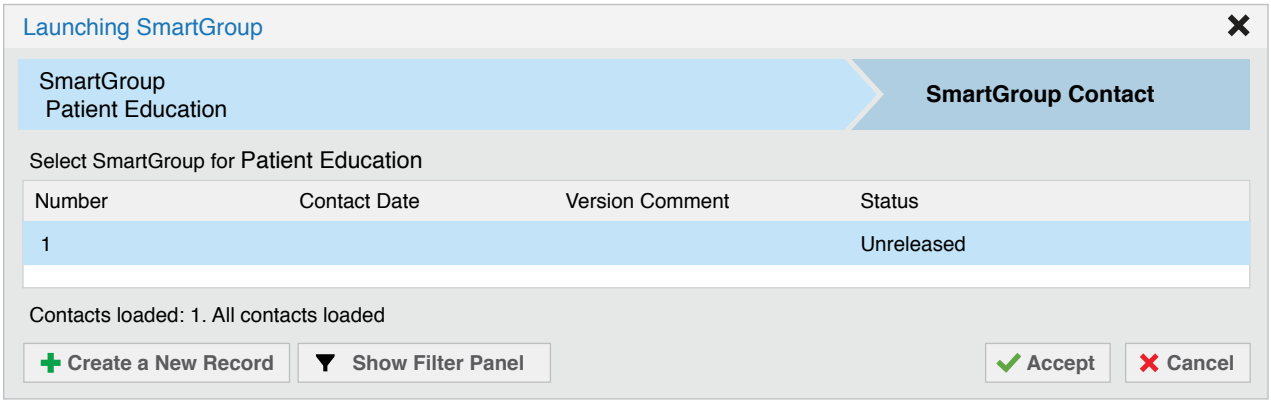
WARNINGS AND PRECAUTIONS

- **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 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

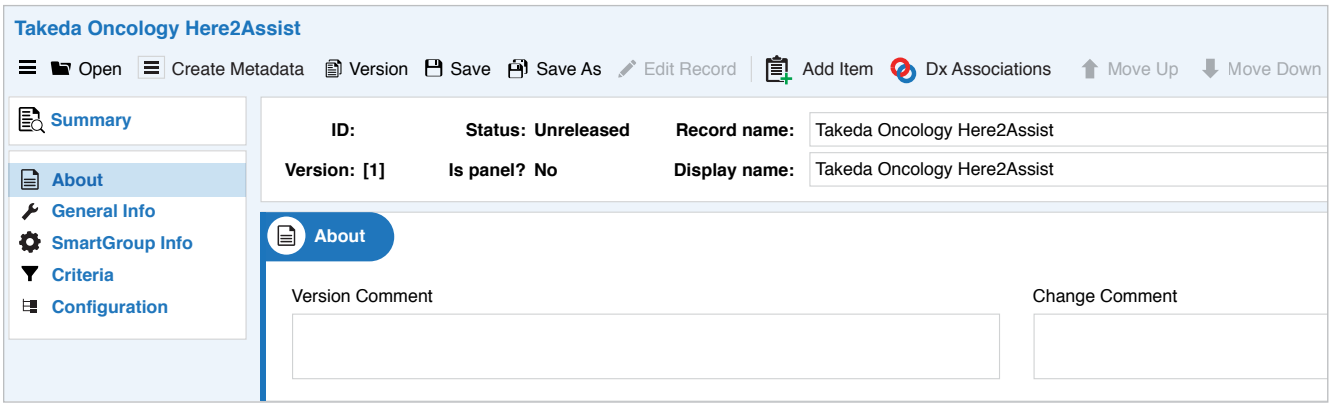
MIMRYLO™ (rusfertide) SmartSet (cont.)

4. Select **Continue**.
5. To add orders to the new SmartGroup, select **Accept**.



Example of contact to show the new SmartGroup information for Patient Education

6. In the **About** section, update any information needed, such as **Version Comment** or **Change Comment**.
7. Select **Add Item** from the toolbar.



Example of creating a new SmartGroup for patient education

IMPORTANT SAFETY INFORMATION (cont.)

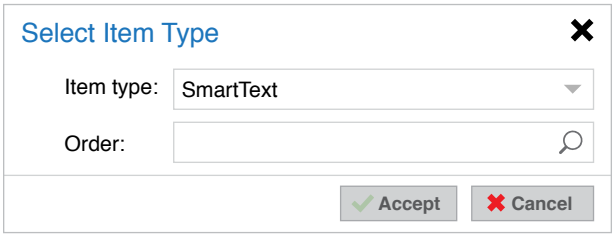
WARNINGS AND PRECAUTIONS (cont.)

- **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.

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

MIMRYLO™ (rusfertide) SmartSet (cont.)

8. In **Select Item Type**, use the dropdown to select the appropriate **Item type**; for example, choose **SmartText**.



Example of setting the Item type as SmartText

9. Search for your desired education to add; for example, TAKEDA ONCOLOGY HERE2ASSIST, and then select **Accept**.
   a. Filing type: Patient Instructions
   b. Display name: Change as needed
10. Select **Accept**.

Example of using SmartText to add Patient Instructions

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.

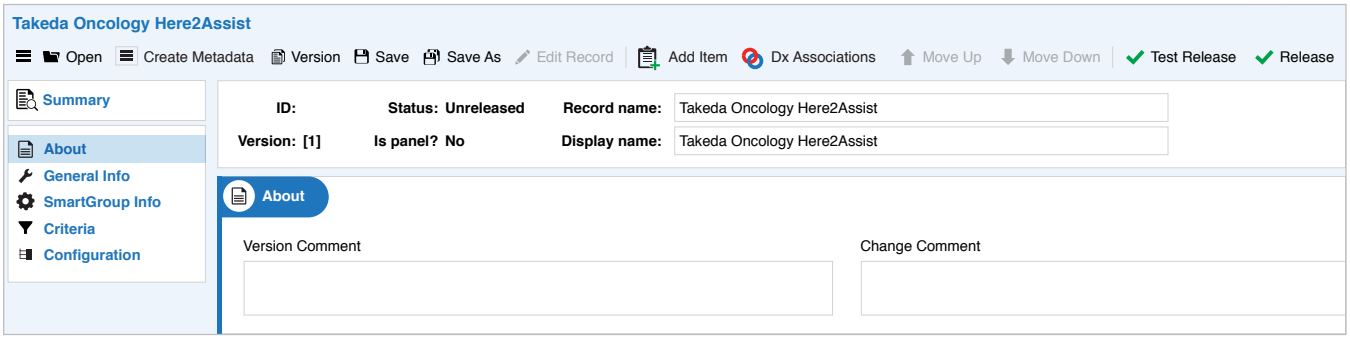
Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

MIMRYLO™ (rusfertide) SmartSet (cont.)

11. When all appropriate **Orders** have been added to this SmartGroup, select **Test Release** to test the SmartGroup.

    Note: *The Test Release version is only visible to the health system IT team; end users cannot see the SmartGroup at this stage.*

12. Once testing is complete, select **Release** for use by all users in the organization.

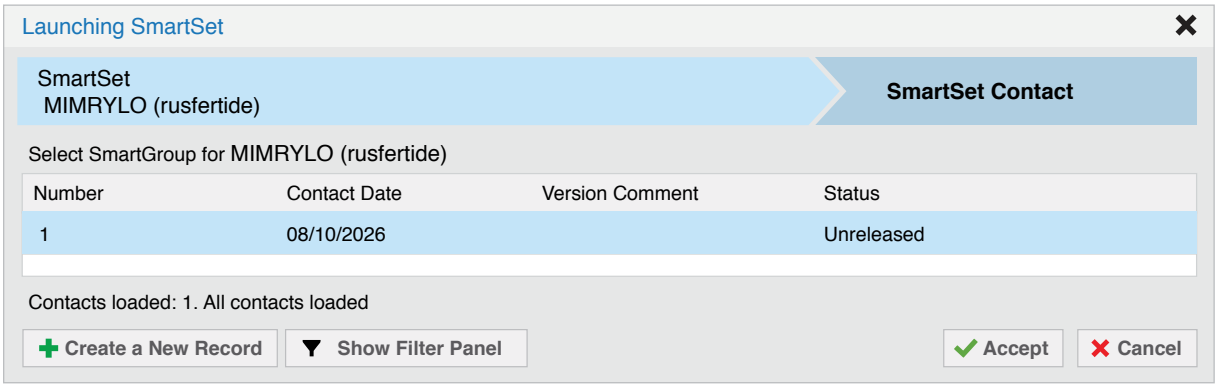


Example of Release buttons in the toolbar for the Patient Education SmartGroup

Creating a New SmartSet

With a new SmartSet, both new and existing SmartGroups can be included, supporting efficiency by leveraging existing, validated content while maintaining consistency across workflows.

1. Search for and select **SmartSet** [PRL].
2. In the **Launching SmartSet** Editor window, select **+ Create a New Record**.



Example of Creating a New Record

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS

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

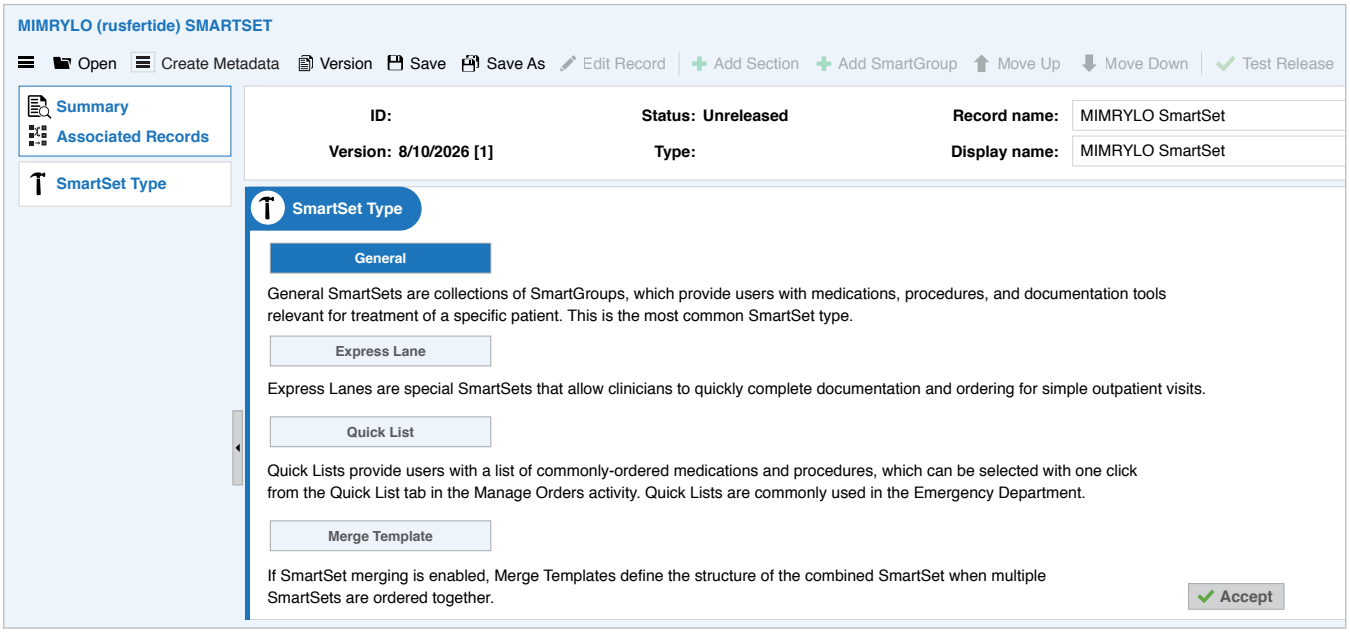
Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

MIMRYLO™ (rusfertide) SmartSet (cont.)

3. Enter an appropriate **Name** for the SmartSet; for example, use MIMRYLO (rusfertide) SmartSet.

   Note: *The Internal ID is auto-generated, and the date will default to the current date.*

4. Select **Continue**.
5. To add SmartGroups to the new SmartSet, select **Accept**.
6. Under **SmartSet Type**, select **General**, and then select **Accept**.



Example of creating a new SmartSet for MIMRYLO (rusfertide) and defining the SmartSet Type

7. The SmartSet Display Name defaults to the SmartSet record name. Change the Display Name as appropriate.

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.
- **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.

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

MIMRYLO™ (rusfertide) SmartSet (cont.)

Adding a SmartGroup to a SmartSet

After the SmartGroup is created, add it to the appropriate section within the SmartSet. In this example, we add a section in which to put our SmartGroup.

1. From the toolbar, select **+ Add Section**.
2. In the Section Configuration, enter a **Name**, such as Medications. Select appropriate options and restrictions per organizational standards. Select **Accept**.
3. Once the Section is created, select **+ Add SmartGroup**.
4. In the **SmartGroup Selector**, enter the **ID** or **Name** from the previous section; for example, use **Labs**, then select **Accept**.
5. When all appropriate SmartGroups have been added to this SmartSet, select **Test Release** to test the SmartSet.
6. Once testing is complete, select **Release** for use by all users in the organization.

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 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

Patient Reports

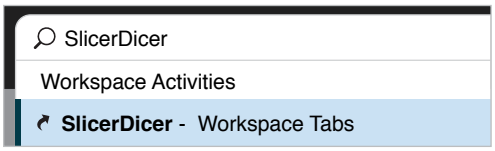
Epic® uses 2 main tools in reporting Slicer/Dicer and Reporting Workbench. Instructions for both tools are included below. Our example here is to identify patients with PV prescribed MIMRYLO™ (rusfertide) who have an HCT ≥45% and may require treatment evaluation.

Using SlicerDicer

SlicerDicer is a reporting tool that enables healthcare professionals to quickly visualize patient population data to assess specific patient groups based on diagnosis, prescriptions, lab results, demographics, and other clinical criteria. The report data displayed can be easily modified by adding or removing criteria, and may be viewed as a summary, a detailed list of patients, or a chart. SlicerDicer queries patient data that are stored as structured or discrete data. The clinical criteria used to generate the report must be defined as searchable terms within the EHR. With SlicerDicer reports, there is a 1-day delay in accessing the most recent patient data entered in the EHR. The following steps may be used to generate a SlicerDicer report to identify patients on MIMRYLO who may benefit from a change in their dose based on the hematocrit result.

Note: *Data models—and the content of those models—may vary by health system, depending on security access.*

1. Search for and select **SlicerDicer**.



Example of searching for the SlicerDicer reporting tool

IMPORTANT SAFETY INFORMATION (cont.)

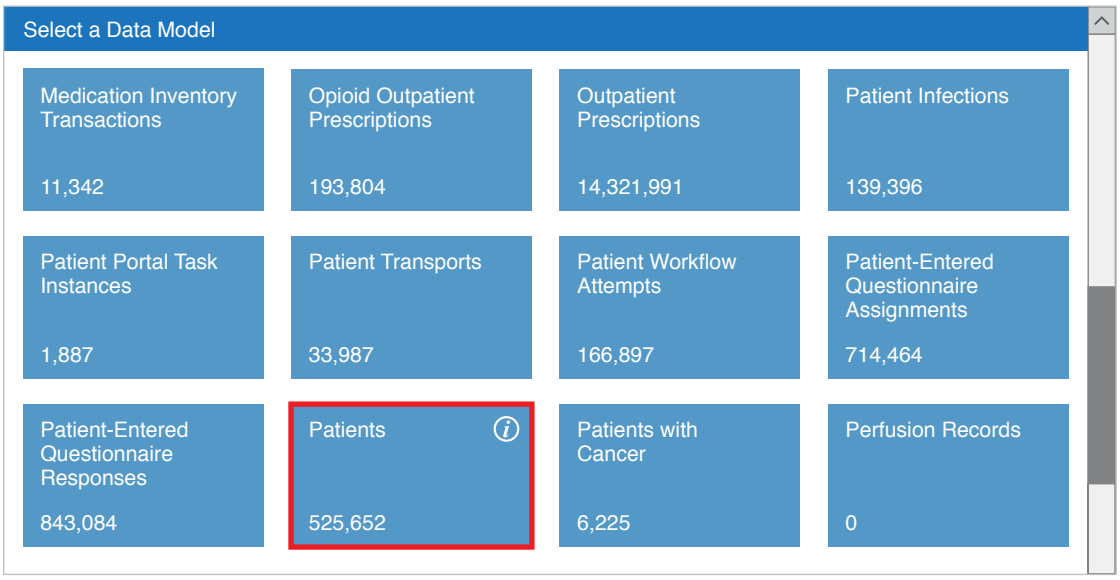
WARNINGS AND PRECAUTIONS (cont.)

- **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.

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

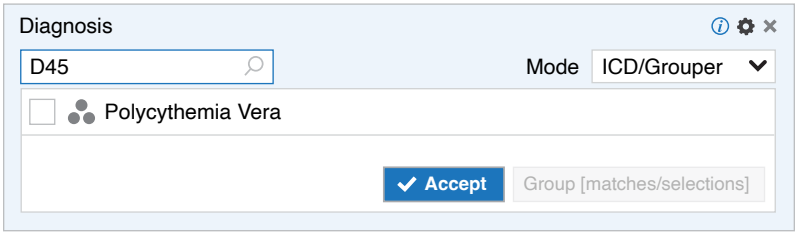
Patient Reports (cont.)

2. Select **Patients Data Model**.



Example of selecting the Patients Data Model

3. Browse Criteria of **Diagnosis**. Search for applicable diagnosis codes, groupers, or SNOMED codes; for example, D45 (Polycythemia Vera).



Example of entering the diagnosis code for Polycythemia Vera

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

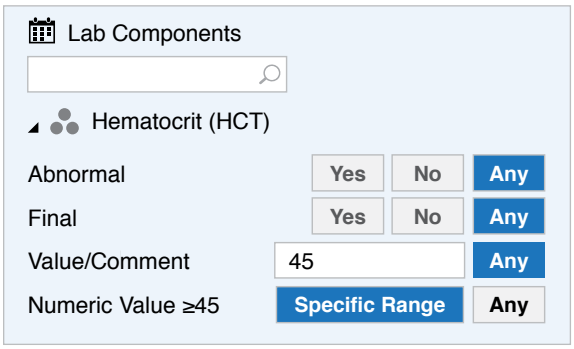
- **Embryo-Fetal Toxicity:** Based on findings from animal reproduction studies, MIMRYLO may cause fetal harm when administered to a pregnant woman. Advise patients to stop taking MIMRYLO if they become pregnant.

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

Mimrylo™ rusfertide for injection

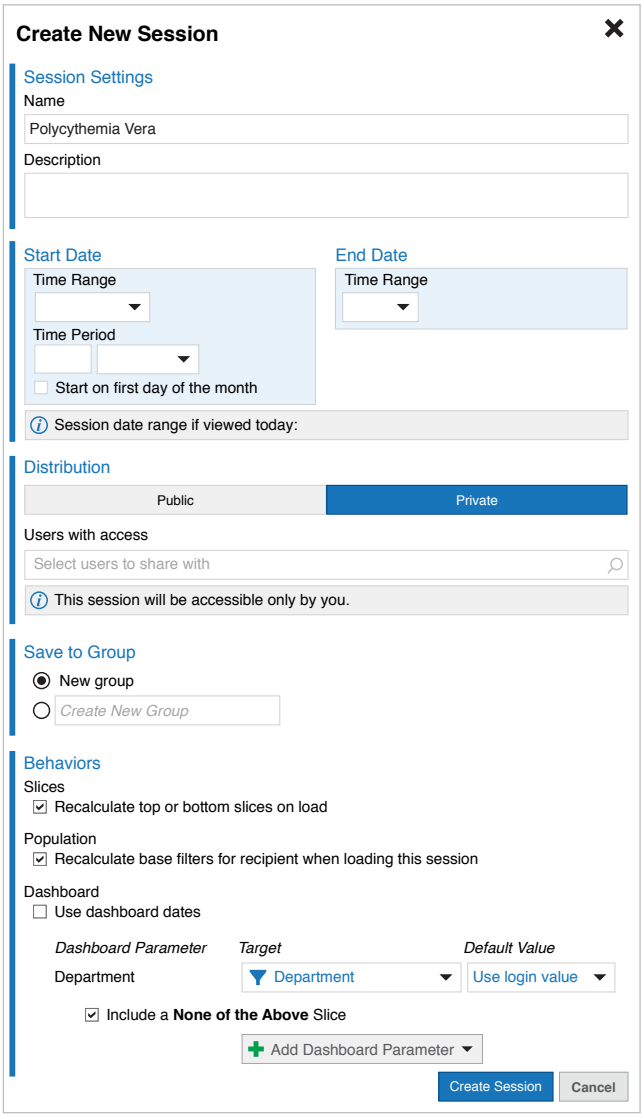
Patient Reports (cont.)

4. Browse criteria of **Medications**, set to MIMRYLO™ (rusfertide).
5. Browse Criteria of **Lab Components**. Search for applicable organization lab components, such as Hematocrit.



Example of setting the Specific Range for Hematocrit (HCT) to ≥45, consistent with prediabetic levels

6. **Dates** > Last 6 months (default).
7. Select **Save As**.
   a. Name as appropriate
   b. Add applicable description to define what the report depicts
   c. Lookback default range as applicable
   d. Based on user security, save as a Public or Private session
8. Select **Create Session**.



Example of initiating a new SlicerDicer session and entering the report Name, Start Date, and End Date

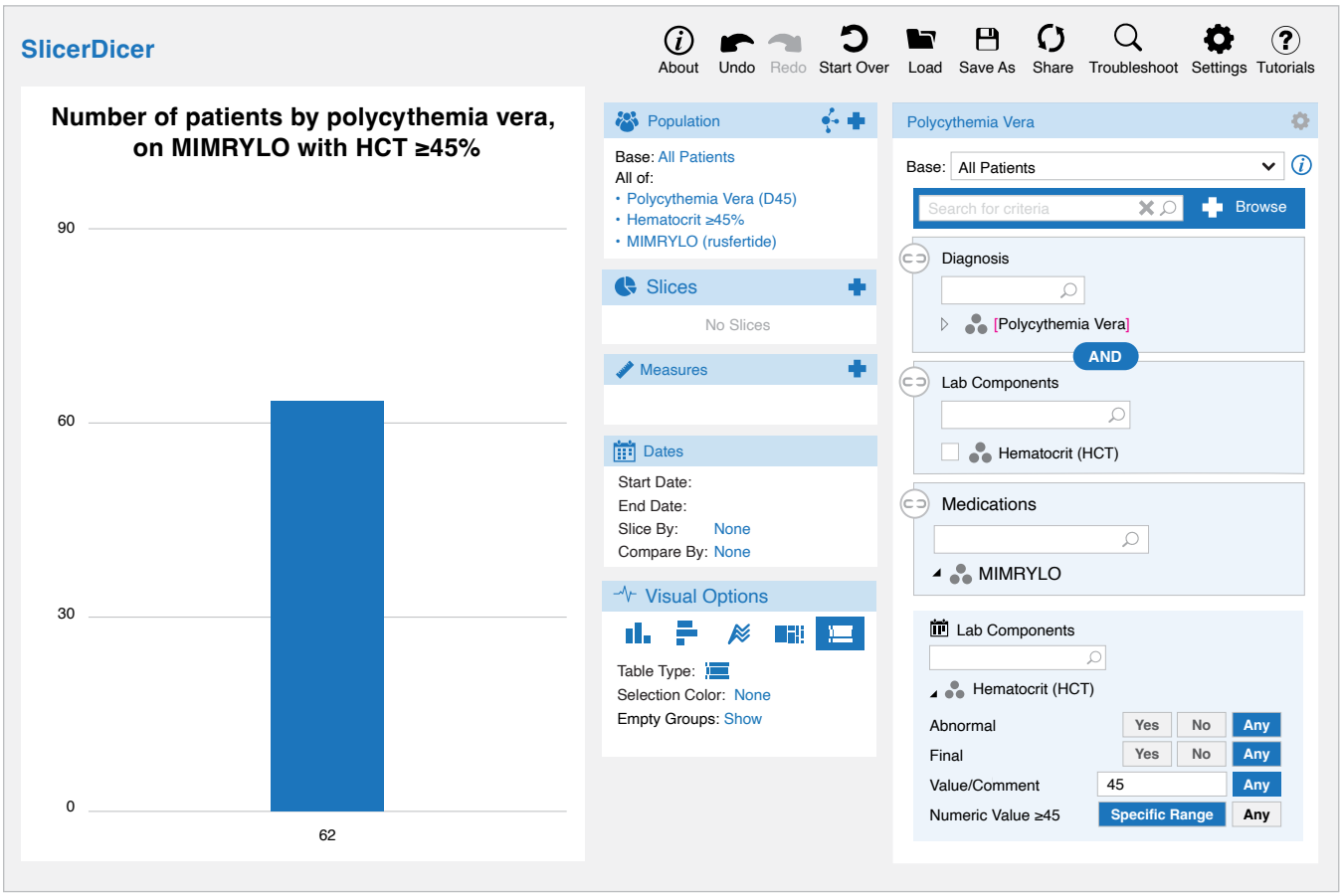
IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS

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

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

Patient Reports (cont.)



Example of the Bar Chart view of the completed SlicerDicer report displaying the Number of patients by polycythemia vera, on MIMRYLO with HCT ≥45%

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.
- **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.

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

Mimrylo™ rusfertide for injection

Patient Reports (cont.)

Using Reporting Workbench

Reporting Workbench offers more robust reporting capabilities that may be customized by the health system's EHR IT team. Reporting Workbench reports include detailed real-time patient-level data that can be filtered and used to trigger outreach and treatment evaluation.

1. **My Reports** > search **Find Patients—Generic Criteria**.

Example of searching My Reports for the template titled Find Patients—Generic Criteria

2. Add all applicable inclusion criteria.
   a. **Diagnosis:** Polycythemia Vera D45

Example of adding Diagnosis as Polycythemia Vera D45

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.

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Mimrylo™ rusfertide for injection

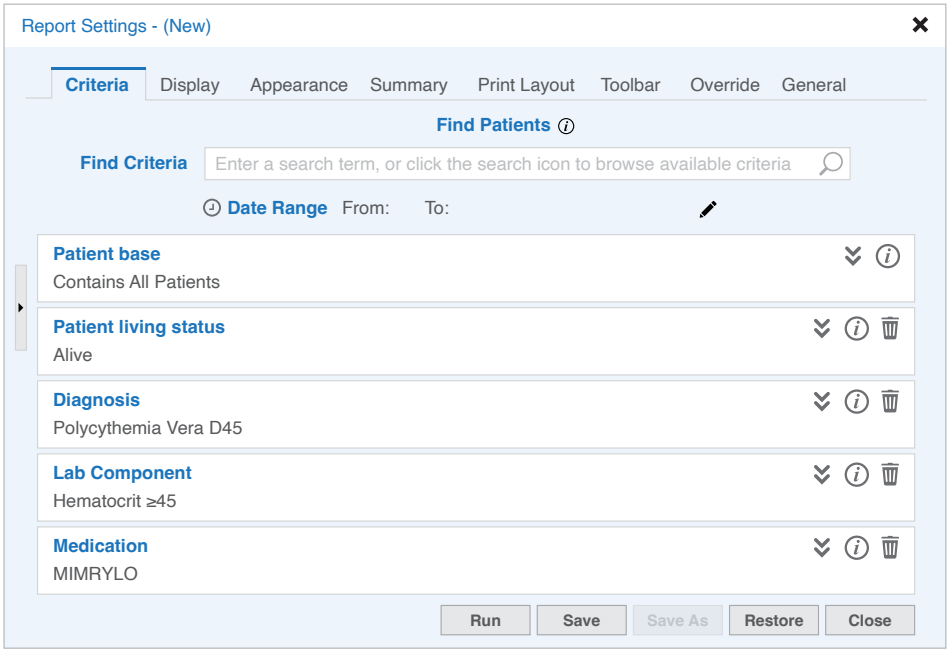
Patient Reports (cont.)

b. **Lab Hematocrit:** ≥45
   i. Base Name: HCT
   ii. Results: Last result value, base name
   iii. Value: ≥45
c. **Medication:** MIMRYLO

3. **Date Range:** Set lookback default range as applicable.

Example of adding Lab Hematocrit as ≥45

Example of adding Medication: MIMRYLO



Example of the criteria tab with desired value and ranges completed

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.

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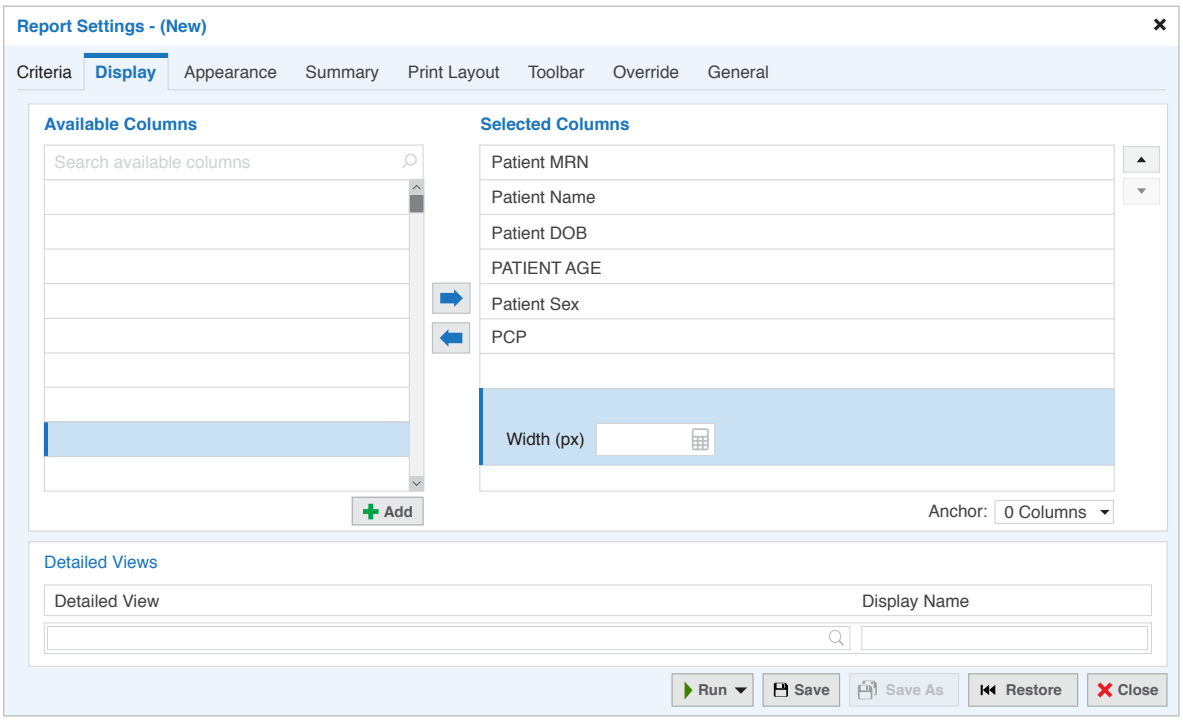
Mimrylo™ rusfertide for injection

Patient Reports (cont.)

4. On the **Display** tab, add applicable column enhancements to filter and sort data.



Example of the display tab demonstrating selection of columns to filter and sort data

IMPORTANT SAFETY INFORMATION (cont.)

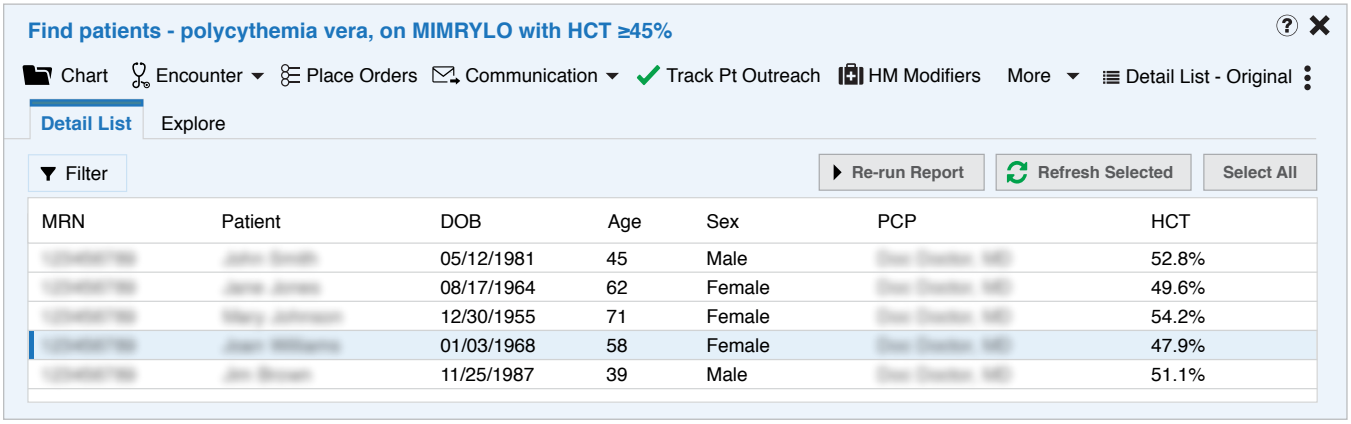
WARNINGS AND PRECAUTIONS (cont.)

- **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.

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

Mimrylo™ rusfertide for injection

Patient Reports (cont.)



MRN	Patient	DOB	Age	Sex	PCP	HCT
[redacted]	[redacted]	05/12/1981	45	Male	[redacted]	52.8%
[redacted]	[redacted]	08/17/1964	62	Female	[redacted]	49.6%
[redacted]	[redacted]	12/30/1955	71	Female	[redacted]	54.2%
[redacted]	[redacted]	01/03/1968	58	Female	[redacted]	47.9%
[redacted]	[redacted]	11/25/1987	39	Male	[redacted]	51.1%

Example of the Patient Detail List view of the report

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.
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Mimrylo™ rusfertide for injection

OurPractice Advisory (OPA)

An OPA is an EHR notification triggered when a patient meets predefined criteria. OPAs are designed to prompt consideration of a specific action (e.g., ordering tests, evaluating/reevaluating treatment, sending a referral, or scheduling follow-up care), and are delivered either as a pop-up alert in real time or as a message sent to a predefined pool or users in-basket.

Health systems determine the OPA content, display options, and intended clinical action in alignment with organizational goals, communication protocols, and system capabilities. Some benefits of using OPAs include:

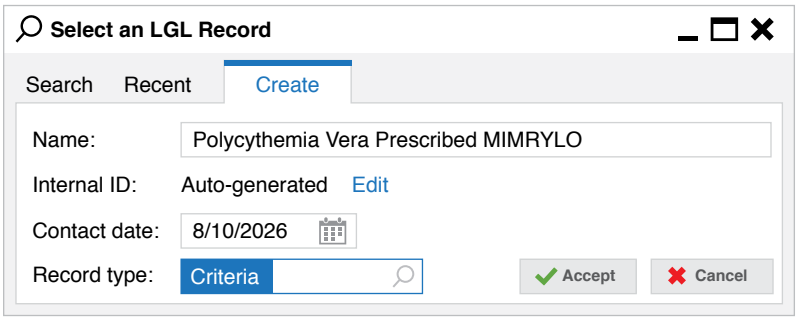
- Supporting healthcare professionals at the point of care with links to relevant clinical information
- Prompting appropriate actions or orders based on treatment protocols
- Improving consistency and standardization of care

Most organizations have an established process for submitting an OPA request to the EHR IT Support Team. While example language may be included in technical configuration steps, healthcare professionals and appropriate health system administrators should determine the final OPA messaging and intended action.

Creating OPA Criteria Records

Inclusion criteria, exclusion criteria, or a combination of both can be used to determine when an OPA is activated or suppressed. Health systems can configure these criteria using available structured data in the EHR to refine alert logic and ensure OPAs apply to appropriate patient populations and care settings.

1. Search for and select **OurPractice Advisory**.
2. Select **Create New Record**.
    a. **Name:** Polycythemia Vera Prescribed MIMRYLO
    b. **Record Type:** Criteria



Example of creating the Criteria Record

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 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

Mimrylo™ rusfertide for injection

OurPractice Advisory (OPA) (cont.)

3. Select **Continue**.
4. On the **Add Criteria Type** screen, select **Lab Components**, **Diagnosis**, and **Medications (include)** as needed.

   Note: *Criteria types may vary by health organization based on system configuration and result availability.*
5. In **Diagnosis**, enter the applicable **Diagnosis Grouper** as listed below. One may need to be created if the applicable grouper is not available.
   a. **Diagnosis Grouper (include):** Polycythemia Vera
6. In **Medications (include)**, enter the applicable medications, **MIMRYLO**.
7. In **Lab Components**, add the applicable lab results.

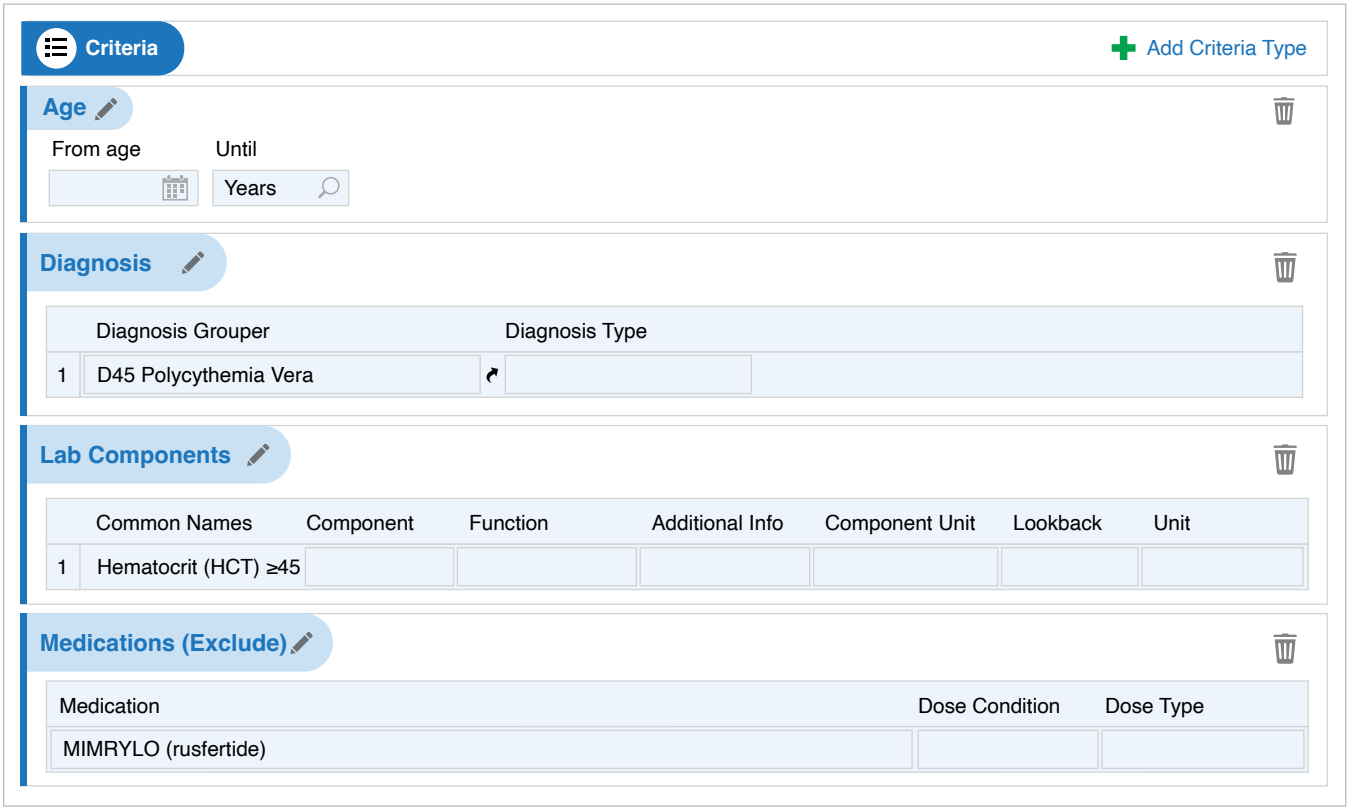
   Note: *Lab results may vary based on how the health organization receives their results.*
   a. **Common Name:** Hematocrit
   b. **Function:** Greater than or equal to (use most recent result)
   c. **Additional Info:** 45
   d. **Lookback unit:** Calendar days
8. Select **Release** and **Save**.

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.

OurPractice Advisory (OPA) (cont.)



Example of a Criteria build

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.

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

Mimrylo™ rusfertide for injection

OurPractice Advisory (OPA) (cont.)

Creating OPA Criteria

Criteria for a patient list that identifies patients with PV prescribed MIMRYLO™ (rusfertide) 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

The information provided is for illustrative purposes only. The final determination of content and implementation is at the discretion of the organization.

Example Timing for When to Display the OPA in the Workflow

- When the patient's chart is opened
- When the patient meets the inclusion criteria during a visit

Example Display Restrictions

OPA should display only to:

- **Example text to be displayed in the OPA**
- **Example actions to be taken upon the OPA notification**
  - Open the appropriate MIMRYLO SmartSet
  - Place an order for MIMRYLO

Creating an OPA Base Record

The OPA base record contains the core advisory information including the advisory name, message text, importance level, and delivery settings.

Creating a base record is a key step in configuring OPAs because it establishes how the message is defined, targeted, and delivered. The base record links the advisory content to associated criteria, triggers, restrictions, and actions, ensuring the OPA is presented appropriately.

1. Search for and select **OurPractice Advisory**.
2. Select **Create New Record**.
   a. **Name:** Polycythemia Vera Prescribed MIMRYLO
   b. **Record type:** Base
3. Select **Continue**.

IMPORTANT SAFETY INFORMATION (cont.)

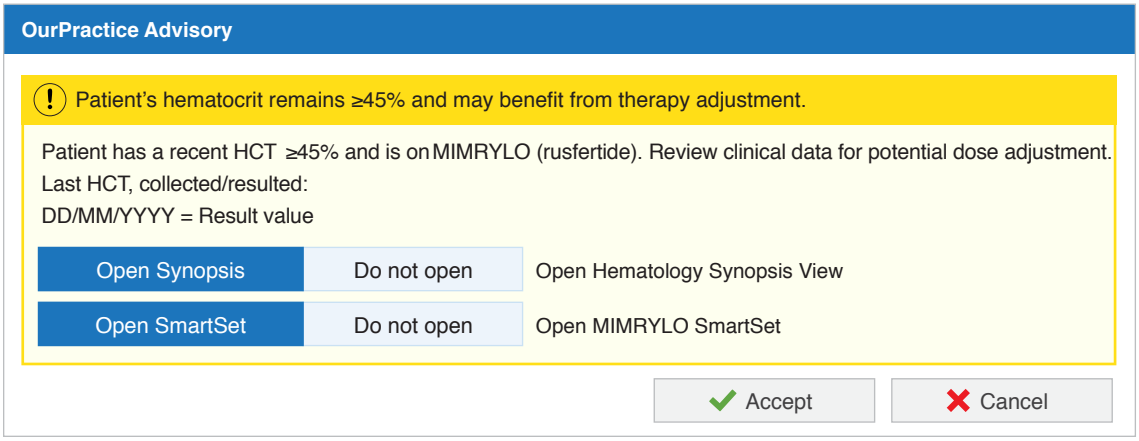
ADVERSE REACTIONS

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

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

OurPractice Advisory (OPA) (cont.)

4. In the **Display** section, add appropriate details; for example:
   a. **Display to user?** Yes
   b. **Unformatted Header text:**
   c. **Body Text:** Patient has a recent HCT ≥45% and is on MIMRYLO. Review clinical data for potential dose adjustment.
   d. **Importance level:** Important
   e. In **Display Last Lab Component**, list organizations **HCT** and Number of Past Results: **1**
5. **In Criteria**, add the appropriate inclusion and exclusion criteria.
6. In **Restrictions**, add applicable restrictions; for example, restrict by department specialty or specialist.
7. In **Triggers**, choose the appropriate trigger, such as open patient chart.
8. In **Actions**, select the appropriate actions to take place; for example, **SmartSet**, **Order Set**, and **Pathways**.
   a. In **SmartSet, Order Sets and Pathways**, list applicable MIMRYLO SmartSet created in previous steps.
9. In **Acknowledge Reasons**, this section can be used as a method to gather additional data or allow the OPA to be hidden.
   a. **Acknowledge Reason:**
      i. Patient refused
      ii. Continue to monitor
      iii. Other
   b. **Default Lockout time:** 2 hours or as appropriate to organization standards



Example of an OPA displayed in the workflow

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.

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

Mimrylo™ rusfertide for injection

Patient Education

Including Orderable Patient Education Resources

When submitting a request to include variable patient education resources as Clinical References, consider including the following information along with the document and/or a link to the resource.

In Epic®, Clinical References are typically managed and updated by the health system's IT department.

To add educational content:

Information	Details to Include
Name or Title of Resource	For example, Takeda Oncology Here2Assist
Contents	Links to the resources to include
Access Level	Define access, such as department-specific, facility-level, or provider-specific access
Method(s) of Delivery to the Patient	• As a handout to print and hand to the patient • Available to send via MyChart®
Define the Audience for the Document	Patients interested in learning more about MIMRYLO treatment
Methods of Use	• Patient-facing to use in discussion with healthcare provider • Added to After Visit Summary® report • Send to patient via MyChart
Specify How Users Will Access the Document	• Via a reference link • Saved as a speed button in provider workflows • As a SmartText or SmartPhrase
Optional Hyperlink (Enabling Patient Access to External Information)	Takeda Oncology Here2Assist here2assist.com or through www.mimrylo.com for the digital enrollment platform

IMPORTANT SAFETY INFORMATION (cont.)

USE IN SPECIFIC POPULATIONS (cont.)

- **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.

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

Mimrylo™ rusfertide for injection

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

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.

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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.)

- **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.

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Mimrylo™ rusfertide for injection

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.)

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.

Please see additional Important Safety Information throughout and on page 46. Please see MIMRYLO (rusfertide) full Prescribing Information.

Mimrylo™ rusfertide for injection

EHR Worksheets (cont.)

Reminder Criteria

Category	✔	Values
OPA Reminder Name Patients with polycythemia vera prescribed MIMRYLO™ (rusfertide) with HCT ≥45%	☐	
Message to Include in OPA Patient has a recent HCT ≥45% and is on MIMRYLO. Review clinical data for potential dose adjustment.	☐	
Clinical Data to Display on OPA	☐	Polycythemia Vera D45
	☐	
Reminder Trigger Criteria	☐	Opening of patient chart
	☐	
Frequency of Reminder	☐	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 (cont.)

ADVERSE REACTIONS

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

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Mimrylo™ rusfertide for injection

EHR Worksheets (cont.)

Reminder Criteria (cont.)

Category	✔	Values	
Clinical Actions to Take Based on the Reminder	☐	Open PV SmartSet ____	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.)

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.

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.

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USE IN SPECIFIC POPULATIONS

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- **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.

References: 1. Vainchenker W, Kralovics R. Genetic basis and molecular pathophysiology of classical myeloproliferative neoplasms. *Blood.* 2017;129(6):667-679. doi:10.1182/blood-2016-10-695940. **2.** Verstovsek S, Pemmaraju N, Reaven NL, et al. Real-world treatments and thrombotic events in polycythemia vera patients in the USA. *Ann Hematol.* 2023;102(3):571-581. doi:10.1007/s00277-023-05089-6. **3.** Verstovsek S, Pemmaraju N, Reaven NL, et al. Real-world treatments and thrombotic events in polycythemia vera patients in the USA. Electronic Supplemental Material. *Ann Hematol.* 2023;102(3):571-581. doi:10.1007/s00277-023-05089-6. **4.** Poullet A, Busque L, Sirhan S, et al. Symptom burden in myeloproliferative neoplasms: clinical correlates, dynamics, and survival impact—a study of 784 patients from the Quebec MPN research group. *Blood Cancer J.* 2025;15(1):51. doi:10.1038/s41408-025-01234-8. **5.** Kuykendall AT, Fine JT, Kremyanskaya M. Contemporary challenges in polycythemia vera management from the perspective of patients and physicians. *Clin Lymphoma Myeloma Leuk.* 2024;24(8):512-522. doi:10.1016/j.clml.2024.04.003. **6.** Randrianarisoa RMF, Ramanandafy H, Mania A, et al. Prevalence and diagnostic performance of iron deficiency in polycythemia. *Hematology.* 2023;28(1):2204621. doi:10.1080/16078454.2023.2204621. **7.** Handa S, Ginzburg Y, Hoffman R, et al. Hepcidin mimetics in polycythemia vera: resolving the irony of iron deficiency and erythrocytosis. *Curr Opin Hematol.* 2023;30(2):45-52. doi:10.1097/MOH.0000000000000747. **8.** Marchioli R, Finazzi G, Specchia G, et al. Cardiovascular events and intensity of treatment in polycythemia vera. *N Engl J Med.* 2013;368(1):22-33. doi:10.1056/NEJMoa1208500. **9.** Poullet A, Busque L, Sirhan S, et al. Symptom burden in myeloproliferative neoplasms: clinical correlates, dynamics, and survival impact—a study of 784 patients from the Quebec MPN Research Group. Supplemental Figure 1. *Blood Cancer J.* 2025;15:51. doi:10.1038/s41408-025-01234-8. **10.** Griesshammer M, Kiladjian JJ, Besses C. Thromboembolic events in polycythemia vera. *Ann Hematol.* 2019;98(5):1071-1082. doi:10.1007/s00277-019-03625-x. **11.** Mesa RA, Miller CB, Thyne M, et al. Differences in treatment goals and perception of symptom burden between patients with myeloproliferative neoplasms (MPNs) and hematologists/oncologists in the United States: findings from the MPN Landmark survey. *Cancer.* 2017;123(3):449-458. doi:10.1002/cncr.30325. **12.** Ginzburg YZ, Feola M, Zimran E, et al. Dysregulated iron metabolism in polycythemia vera: etiology and consequences. *Leukemia.* 2018;32(10):2105-2116. doi:10.1038/s41375-018-0207-9. **13.** Bennett C, Jackson VE, Pettikiriarachchi A, et al. Iron homeostasis governs erythroid phenotype in polycythemia vera. *Blood.* 2023;141(26):3199-3214. doi:10.1182/blood.2022016779. **14.** Cleveland Clinic. Iron-Deficiency Anemia. Revised December, 2024. Accessed March, 2026. Available at: https://my.clevelandclinic.org/health/diseases/22824-iron-deficiency-anemia. **15.** Visweshwar N, Fletcher B, Jaglal M, et al. Impact of phlebotomy on quality of life in low-risk polycythemia vera. *J Clin Med.* 2024;13(16):4952. doi:10.3390/jcm13164952.

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