Romvimza® (vimseltinib) 30mg Capsules

# Epic® Electronic Health Record (EHR) Instructions

## HOW TO UPDATE ORDER SETS WITH ROMVIMZA® (vimseltinib) IN THE EPIC EHR SYSTEM

### INDICATIONS AND USAGE

ROMVIMZA is indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.

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# Overview and limitations

This document is intended to provide health systems with instructions to update order sets with ROMVIMZA in the Epic EHR system, within the approved indications and consistent with prescribing information.

These instructions are specific to ROMVIMZA, a kinase inhibitor indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.

This guide is for the Epic EHR system. This guide is not appropriate for other conditions, treatments, or therapeutic areas or for other EHR systems.

The process outlined in this document is variable, and not all steps will apply to every organization. Any steps or settings that are not part of an organization's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The organization is solely responsible for implementing, testing, monitoring, and ongoing operation of any EHR tools.

## Background and indication

Deciphera Pharmaceuticals, LLC, has identified a need to help health systems update their EHR order sets with ROMVIMZA.

### INDICATIONS AND USAGE

ROMVIMZA® (vimseltinib) is a kinase inhibitor indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.

# Considerations

Order sets are commonly used in the management of oncology patients. After their initial release, order sets may benefit from a clinical update. The optimization of order sets, referred to as protocols, order sets, or regimens in the Epic EHR, is a common process and provides an opportunity to incorporate treatment updates. Order sets are typically modified at the health system level to help reduce practice variation.

Typically, an organization will conduct a clinical review to confirm and approve the suggested optimization. Various stakeholders may participate in reviewing order set optimization requests prior to implementation.

## Suggested order set content

Key clinical details from the ROMVIMZA Prescribing Information are included below and may be incorporated as part of the order set update based on steps in the Instructions section that follows. The Prescribing Information data in this section are only suggestions, and it is strongly recommended that clinical and operational leadership align the order set contents with the expectations and goals of the organization. The organization may add or edit any details as desired to align with governing EHR policies and standards.

## Dosage and administration

The recommended dosage of ROMVIMZA is 30 mg orally taken twice weekly, with a minimum of 72 hours between doses, as directed on the blister package. Instruct patients to follow the schedule on the blister package and to take ROMVIMZA on the same days each week.

- ROMVIMZA may be taken with or without food.
- Swallow ROMVIMZA capsules whole. Do not open, break, or chew the capsules.
- If a dose is missed by 48 hours or less, take the missed dose as soon as possible and take the next dose on its regularly scheduled day. If a dose is missed by more than 48 hours, skip the missed dose, and take the next dose on its regularly scheduled day.
- If vomiting occurs within 30 minutes of taking a dose, repeat that dose. Otherwise, take the next dose on its regularly scheduled day.

## Dosage and administration (continued)

### Dose modifications for adverse reactions

The recommended dose reductions for adverse reactions are provided in Table 1.

TABLE 1: RECOMMENDED DOSE REDUCTIONS

| Dose reduction | Twice weekly dose |
|---|---|
| **First** | 20 mg |
| **Second** | 14 mg |

Permanently discontinue ROMVIMZA in patients who are unable to tolerate 14 mg orally twice weekly.

The recommended dosage modifications for hepatotoxicity are summarized in Table 2.

# Considerations (continued)

TABLE 2: RECOMMENDED DOSAGE MODIFICATIONS FOR HEPATOTOXICITY

| Hepatotoxicity severity | ROMVIMZA dosage modifications |
|---|---|
| **AST and/or ALT increases >3–5 times ULN and total bilirubin increases up to 2 times ULN**<br>**OR**<br>**Total bilirubin increases up to 2 times ULN** | Withhold ROMVIMZA until AST and ALT resolve to baseline or ≤3 times ULN, and bilirubin resolves to baseline.<br>Resume at the next lower dose level once Hy's law has been definitively ruled out.<br>Permanently discontinue if adverse reaction does not resolve within 4 weeks. |
| **AST and/or ALT increases >3–5 times ULN, and total bilirubin increases >2 times ULN or INR >1.5 and ALP <2 times ULN**<br>**OR**<br>**Total bilirubin increases >2 times ULN** | Withhold ROMVIMZA until AST and ALT resolve to baseline or ≤3 times ULN, and bilirubin resolves to baseline.<br>Resume at the next lower dose level once Hy's law has been definitively ruled out.<br>Permanently discontinue if adverse reaction does not resolve within 4 weeks. |
| **AST and/or ALT increases >5–8 times ULN, and total bilirubin ≤ULN and without clinical symptoms** | Withhold ROMVIMZA until AST and ALT resolve to ≤3 times ULN or baseline.<br>Resume at the next lower dose level.<br>Permanently discontinue if adverse reaction does not resolve within 4 weeks. |
| **AST and/or ALT increases >5–8 times ULN and total bilirubin increase >ULN, or INR >1.5, or ALP >2 times ULN** | Permanently discontinue ROMVIMZA. |
| **AST and/or ALT increases >8 times ULN** | Permanently discontinue ROMVIMZA. |

## Dosage Modification for P-glycoprotein (P-gp) Substrates

Avoid concomitant use of ROMVIMZA with P-gp substrates. If concomitant use of a P-gp substrate is unavoidable, administer ROMVIMZA at least 4 hours before taking the P-gp substrate unless otherwise recommended in the substrate Prescribing Information.

There are no known contraindications for ROMVIMZA.

ALP=alkaline phosphatase; ALT=alanine aminotransferase; AST=aspartate aminotransferase; INR=international normalized ratio; ULN=upper limit of normal.

# Instructions

An existing Beacon protocol may be used as the foundation for a new one. Consider modifying an existing protocol that includes ROMVIMZA as a starting template, while saving the original protocol.

## There are 3 main steps to updating a Beacon protocol in the Epic EHR system

- **Step 1:** Create or update the order groups. As part of this step, multiple order groups related to ROMVIMZA may be created/updated. Order groups for ROMVIMZA may be created, as well as for any other desired order groups (eg, treatment conditions, monitoring and hold parameters, warnings and precautions, schedulable orders, labs, health care professional [HCP] communications). Review the organization's governing rules and principles regarding order sets and adjust the optimization appropriately.
- **Step 2:** Add links for the Prescribing Information and other resources to the medication record.
- **Step 3:** Add the order groups created in Step 1 to the new Beacon protocol.

### Step 1: Create or update the order groups

1. Review the Regimen Category Order Group to confirm Medications, Treatment Conditions, and Supportive Medications are values in the category list.
2. Select the Order Group Builder (Admin > Beacon Admin > Order Group Builder).
3. Create the new order groups (see detailed examples below).

#### Order group 1: ROMVIMZA

1. Review the Regimen Category Order Group to confirm Medications is a value in the category list.
2. Select the Order Group Builder (Admin > Beacon Admin > Order Group Builder).
3. Create a new order group named "ROMVIMZA for tenosynovial giant cell tumor (TGCT)."
4. Set the default category to Medications.
5. Add the details for ROMVIMZA to the order group:
   - Right click in the empty field at the bottom of the window.
   - Select Add Orders > choose ROMVIMZA.
   - Complete the medication details for ROMVIMZA. Details may include Sig, dose, route, frequency, and admin instructions (see the Dosage and Administration section starting on page 3. For dose modifications for adverse reactions, see section 2.2 of the ROMVIMZA PI, for dosage modification for P-glycoprotein (P-gp) substrates, see section 2.3 of the ROMVIMZA PI):

# Instructions (continued)

The recommended dosage of ROMVIMZA is 30 mg orally taken twice weekly, with a minimum of 72 hours between doses, as directed on the blister package. Instruct patients to follow the schedule on the blister package and to take ROMVIMZA on the same days each week.

- ROMVIMZA may be taken with or without food.
- Swallow ROMVIMZA capsules whole. Do not open, break, or chew the capsules.
- If a dose is missed by 48 hours or less, take the missed dose as soon as possible and take the next dose on its regularly scheduled day. If a dose is missed by more than 48 hours, skip the missed dose, and take the next dose on its regularly scheduled day.
- If vomiting occurs within 30 minutes of taking a dose, repeat that dose. Otherwise, take the next dose on its regularly scheduled day.

6. Once all the desired information is added, release and publish the order group.

### Additional order groups

Add the other desired order groups for ROMVIMZA (eg, treatment conditions, monitoring and hold parameters, warnings and precautions, supportive care, schedulable orders, labs, HCP communications) used in the treatment regimen. Consider the prescribing information below for other order groups:

- Monitor liver tests, including AST, ALT, total bilirubin, direct bilirubin, ALP, and gamma-glutamyl transferase (GGT), prior to initiation of ROMVIMZA, twice a month for the first two months and once every 3 months for the first year of therapy and as clinically indicated thereafter.
- For dosage modifications for adverse reactions, see section 2.2 of the ROMVIMZA PI.
- For dosage modification for P-glycoprotein (P-gp) substrates, see section 2.3 of the ROMVIMZA PI.
- There are no known contraindications for ROMVIMZA.
- For warnings and precautions, see section 5 of the prescribing information.
- For adverse reactions, see section 6 of the prescribing information.

# Instructions (continued)

## Step 2: Add links for the Prescribing Information and other resources to the medication record

1. Log in to the Medication Master File (ERX) with authorized user credentials.
2. Use the search feature in the Medication Master File to search for and select ROMVIMZA.
3. Select the Patient Medication References screen and create 2 new rows:
   - Row 1: For Display Name, enter "ROMVIMZA Prescribing Information." In the Text field, enter "See URL for additional ROMVIMZA prescribing information." In the URL field, enter this hyperlink: **https://www.romvimzahcp.com/content/files/prescribing-information.pdf**
   - Row 2: For Display Name, enter "Additional ROMVIMZA Resources for HCPs and Patients." In the Text field, enter "See URL for additional resources for HCPs and patients." In the URL field, enter this hyperlink: **https://www.romvimzahcp.com/resources**
4. Save the medication record.
5. Release the record to the production environment after completing testing.

## Step 3: Add the order groups created in Step 1 to the new Beacon protocols

1. Click the Epic logo > Admin > Beacon Admin > Protocol Builder.
2. Search for Beacon protocols using the search query and entering search terms specific to each indication. Note that an existing ROMVIMZA protocol may be available to optimize. Note: The existing Beacon protocol will only serve as a template for the new ROMVIMZA protocol. If the original protocol used to create the new ROMVIMZA protocol includes ROMVIMZA, confirm it is retired or removed from the EHR production system according to the organization's EHR governing principles.
3. Add all the newly created order groups from Step 1 to the treatment regimen (order groups with ROMVIMZA, and other order groups) to the treatment regimen calendar and protocol.
4. Update the Beacon protocol names to:
   - "ROMVIMZA for tenosynovial giant cell tumor (TGCT)"
5. Update the Beacon protocol descriptions to:
   - "ROMVIMZA for treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity"
6. Click Save.
7. Release the Beacon protocol to the production environment after completing testing.

# Notes

- The customer (eg, physician, medical group, integrated delivery network) shall be solely responsible for the implementation, testing, and monitoring of the instructions to ensure proper orientation in each customer's EHR system.
- Capabilities, functionality, and setup (customization) for each EHR system may vary. Deciphera Pharmaceuticals, LLC, shall not be responsible for revising the implementation instructions it provides to any customer if the customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by Deciphera Pharmaceuticals, LLC.
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# IMPORTANT SAFETY INFORMATION

## WARNINGS AND PRECAUTIONS

**Hepatotoxicity:**

- Cases of serious and fatal liver injury have occurred with the use of another kinase inhibitor that targets CSF1R. Serious and fatal liver injury have not been observed with ROMVIMZA.
- Elevated AST and ALT can occur with ROMVIMZA.
- Avoid ROMVIMZA in patients with pre-existing increased serum transaminases; total bilirubin or direct bilirubin (>ULN); or active liver or biliary tract disease, including ALP.
- Monitor liver function tests prior to initiation of ROMVIMZA, twice a month for the first two months and once every 3 months for the first year of therapy and as clinically indicated thereafter. Withhold and reduce the dose, or permanently discontinue ROMVIMZA based on the severity of the hepatotoxicity.

**Embryo-Fetal Toxicity:**

- ROMVIMZA may cause fetal harm when administered to pregnant women. Advise pregnant women on the potential risk to the fetus.
- Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with ROMVIMZA and for 1 month after the last dose.

**Allergic Reactions to FD&C Yellow No. 5 (Tartrazine) and No. 6 (Sunset Yellow FCF):**

- ROMVIMZA 20 mg capsule contains FD&C Yellow No. 5 (tartrazine) which may cause allergic reactions (including bronchial asthma) in certain susceptible patients. FD&C Yellow No. 5 (tartrazine) sensitivity is frequently seen in patients who also have aspirin sensitivity.
- Advise patients that ROMVIMZA 14 mg and 20 mg capsules contain FD&C Yellow No. 6 (Sunset Yellow FCF), which may cause allergic reactions.

**Increased Creatinine without Affecting Renal Function:**

- Increases in serum creatinine can occur with the use of ROMVIMZA. These increases in serum creatinine may not be associated with changes in renal function. Increases in creatinine reversed upon ROMVIMZA discontinuation. During ROMVIMZA treatment, use alternative measures that are not based on serum creatinine to assess renal function.

**Adverse Reactions:**

The most common (≥20%) adverse reactions, including laboratory abnormalities that occurred in patients receiving ROMVIMZA were increased AST, periorbital edema, fatigue, rash, increased cholesterol, peripheral edema, face edema, decreased neutrophils, decreased leukocytes, pruritus, and increased ALT.

**Drug Interactions:**

- P-glycoprotein (P-gp) substrates: Avoid concomitant use of ROMVIMZA with P-gp substrates. If concomitant use cannot be avoided, take ROMVIMZA at least 4 hours prior to P-gp substrates.
- Breast Cancer Resistance Protein (BCRP) substrates: Avoid concomitant use of ROMVIMZA with BCRP substrates.
- Organic Cation Transporter 2 (OCT2) substrates: Avoid concomitant use of ROMVIMZA with OCT2 substrates.
- Concomitant use of vimseltinib with P-gp substrates, BCRP substrates or OCT2 substrates may increase exposure of these substrates.

**Lactation:** Advise females not to breastfeed during treatment with ROMVIMZA.

**Please click for the full Prescribing Information.**

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