



Epic[®] Electronic Health Record (EHR) Instructions

INSTRUCTIONS TO CREATE A PATIENT LIST TO IDENTIFY PATIENTS DIAGNOSED WITH TENOSYNOVIAL GIANT CELL TUMOR (TGCT) IN THE EPIC EHR SYSTEM

INDICATIONS AND USAGE

ROMVIMZA (vimseltinib) 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.



Overview and limitations

This document is intended to provide health systems with instructions to create a patient list in the Epic® EHR system to identify adult patients diagnosed with tenosynovial giant cell tumor (TGCT).

This guide is for the Epic EHR system and 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 the ongoing operation of any EHR tools.

While EHRs may assist providers in identifying appropriate patients for consideration of assessment, treatment, and referral, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and Deciphera Pharmaceuticals, LLC, shall have no liability thereto.

Please see Page 5 for additional important information on the use of this document.

Suggested criteria

- Age: 18 years and older
- Tenosynovial giant cell tumor (TGCT) possible diagnostic codes*:
 - D21.0 – Benign neoplasm of connective and other soft tissue of head, face and neck
 - D21.10 – Benign neoplasm of connective and other soft tissue of unspecified upper limb, including shoulder
 - D21.20 – Benign neoplasm of connective and other soft tissue of unspecified lower limb, including hip
 - D21.9 – Benign neoplasm of connective and other soft tissue, unspecified
 - D48.1 – Neoplasm of uncertain behavior of connective and other soft tissue
 - M12.20 – Villonodular synovitis (pigmented), unspecified site
 - M12.219 – Villonodular synovitis (pigmented), unspecified shoulder
 - M12.229 – Villonodular synovitis (pigmented), unspecified elbow
 - M12.239 – Villonodular synovitis (pigmented), unspecified wrist
 - M12.249 – Villonodular synovitis (pigmented), unspecified hand
 - M12.259 – Villonodular synovitis (pigmented), unspecified hip
 - M12.269 – Villonodular synovitis (pigmented), unspecified knee
 - M12.279 – Villonodular synovitis (pigmented), unspecified ankle and foot
 - M12.28 – Villonodular synovitis (pigmented), other specified site
 - M12.29 – Villonodular synovitis (pigmented), multiple sites
- Optional criterion: Medications, for example, pain/steroid medications, Turalio® (pexidartinib), imatinib, Tasigna® (nilotinib)†

*The list of TGCT possible diagnostic codes is not exhaustive; other codes may be used. Diagnostic codes alone may not confirm a TGCT diagnosis.

†Not indicated for TGCT, but referenced in TGCT guidelines.

Note: Consider running the report on a regular basis. Once the initial report has been created, it can be saved for future use, and subsequent reports can be rerun. Running reports over time allows an institution or practice to identify potential new patients meeting the inclusion criteria.

Instructions

Consider Reporting Workbench or SlicerDicer to create the patient list. Depending on availability, consider the preferred reporting tool to complete the patient report. Consult your organization if administrative user rights are required to access the reporting solutions.

Option 1: Reporting Workbench

1. Access Reporting Workbench (click the Epic logo > Reports > My Reports) or use the chart search feature.
2. In the search field, enter “generic criteria” to find the reporting template.
3. Select the Find Patients - Generic Criteria report template and click New.
4. In the Report Settings window, select the Criteria tab and add the first criterion to the query.
5. In the Find Criteria search field, enter “age”.
6. Select the Age in years criterion and set the age range to 18 years and older.
7. In the Find Criteria field, enter “diagnosis” and select the Diagnosis by Code criterion.
8. Enter and select the Tenosynovial Giant Cell Tumor (TGCT) diagnoses ICD-10 codes D21.0, D21.10, D21.20, D21.9, D48.1, M12.20, M12.219, M12.229, M12.239, M12.249, M12.259, M12.269, M12.279, M12.28, and M12.29.
9. In the Find Criteria search field, enter “medication”.
10. Select the Meds: Current (by exact medication) criterion.
11. Enter and select the desired medications. Alternatively, consider searching by pharmaceutical class or enter and select individual medications (Note: this name may vary depending on the compendium).
12. Confirm the logic to include the age, any of the diagnosis codes (optionally, add the medication(s)).
13. Select the Display tab to set all display columns for the report. Select all desired columns and click the right arrow to drag to the Selected Columns pane. Consider current and past medications, encounter history, and other desired patient information to display in the report.
14. In the General tab, enter the desired Report Name (for example “Adult Patients with TGCT”) and a Description. Results can be shared with selected users or pools.
15. Click Save and Run to create the patient list. The list will display all patients matching the criteria.

Instructions (continued)

Option 2: SlicerDicer

1. Access SlicerDicer (click the Epic logo > Reports > SlicerDicer).
2. Depending on availability, select the Patients model (the number in the data model box represents the base population and number of records in the data model).
3. In the right-hand column, select the desired patient base, for example All Patients (Note: First-time users of SlicerDicer may see a tutorial prompted during initial use. Complete the tutorial and continue with the steps described in this resource).
4. In the Search for Criteria field, enter “age”. Alternatively, the + Browse button can also be used. When using the + Browse button, a new screen will display where the filter criterion and inclusion/exclusion status can be selected.
5. Select the Age in years criterion and set the age range to 18 years and older.
6. In the Search for Criteria field, enter “diagnosis” and select the Diagnosis by Code criterion.
7. Set the Mode to ICD/Grouper and enter and select the Tenosynovial Giant Cell Tumor (TGCT) diagnoses ICD-10 codes D21.0, D21.10, D21.20, D21.9, D48.1, M12.20, M12.219, M12.229, M12.239, M12.249, M12.259, M12.269, M12.279, M12.28, and M12.29.
8. In the Search for Criteria field, enter “medications” and select the Medications criterion.
9. Enter and select the desired medications. Alternatively, consider searching by pharmaceutical class or enter and select individual medications (Note: this name may vary depending on the compendium).
10. Confirm the logic to include the age, any of the diagnosis codes (optionally, add the medication(s)).
11. Click the last icon with the detail table in the Visual Option section to see the query results.
12. The results can be exported to Reporting Workbench by right-clicking the bar with the patient results and selecting Show Slice in Reporting Workbench.
13. In Reporting Workbench, select the Display tab to set all display columns for the report. Select all desired columns and click the right arrow to drag to the Selected Columns pane. Consider current and past medications, encounter history, and other desired patient information to display in the report.
14. In the General tab, enter the desired Report Name (for example “Adult Patients with TGCT”) and a Description. Results can be shared with selected users or pools.
15. Click Save and Run to create the patient list. The list will display all patients matching the criteria.

Important Information

- 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.
- While Deciphera Pharmaceuticals, LLC, tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems, and Deciphera Pharmaceuticals, LLC, shall have no liability thereto.
- The instructions have not been designed for, and are not tools and/or solutions for, meeting Advancing Care Information and/or any other quality/accreditation requirement.
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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 (vimseltinib).
- 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.