Romvimza™ (vimseltinib) 30mg Capsules

Access & Coverage Quick Reference Guide

Information to assist with patient access to ROMVIMZA

IMPORTANT NOTE: It is the healthcare provider's responsibility to determine the appropriate medical diagnosis, codes, and treatment and to submit valid and accurate claims for products and services rendered. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. It is the responsibility of the provider to contact third-party payers for specific information on their coding, coverage, and payment policies. Deciphera Pharmaceuticals provides this information and materials for the purposes of assisting healthcare providers. The responsibility of determining coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains with the healthcare provider. Even if all information provided is valid and accurate, there is not a guarantee of coverage or reimbursement from payers for any product or service.

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.

SELECT 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.

Please see additional Safety Information throughout and click for the full Prescribing Information.

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Deciphera AccessPoint™ can provide support to help address common access issues

Approval criteria may vary by insurance plan, but will likely require:

- The appropriate ICD-10-CM code
- Documentation of the patient's TGCT diagnosis and prognosis
- Documentation of the patient's previous surgeries and treatments, if any, for TGCT
- Documentation or attestation that surgical resection will potentially cause worsening functional limitation or severe morbidity

Key codes for completing a ROMVIMZA medical exception request or prior authorization*

The listing contains nonbillable diagnosis codes that indicate a subcategory. When submitting information to an insurance plan, only codes with a full number of required characters are permissible. A complete list of all ICD-10 codes can be found at ICD10data.com

National Drug Code (NDC) for ROMVIMZA		
Strength	**Packaging configuration**	**NDC**
30 mg	8 count blister in wallet	73207-304-40
20 mg	8 count blister in wallet	73207-303-40
14 mg	8 count blister in wallet	73207-302-40

ICD-10-CM Codes for TGCT
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

ICD-10-CM = International Classification of Diseases, 10th Revision, Clinical Modification.

* These codes are provided for informational purposes only. Additional codes pertaining to TGCT are possible. Healthcare providers have the responsibility to assure claims and codes submitted are accurate, complete, and applicable.

Reference: ICD10Data.com. Updated 2024. Accessed November 5, 2024. https://www.icd10data.com/.

Deciphera AccessPoint offerings can help eligible patients get started without delay

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To support timely patient access to ROMVIMZA, Deciphera AccessPoint can:

- **Verify** payer-specific coverage requirements
- **Provide** information on the process, including medical exceptions and PAs
- **Track** the status of medical exceptions or PAs
- **Update** practices and patients throughout the process

Insurance delays?

When pending insurance decisions or interruptions in coverage threaten to delay treatment, ask Deciphera AccessPoint about our temporary supply programs.

- The **Rapid Start program** provides medication to eligible patients dealing with coverage delays
- The **Bridge program** provides medication to eligible patients experiencing lapses in coverage

Both programs provide eligible patients with a 14-day supply of medication with up to 5 refills, for up to 84 days of treatment.†

If your patient does not have insurance, or if their health plan doesn't cover ROMVIMZA, they may qualify for free medication.† Patients can visit DecipheraAccessPoint.com for more information.

†Terms and conditions apply.

Deciphera AccessPoint can help answer your questions about patient access, so count on us when you need support.

- From medical exception requests to prior authorizations (PAs), we can help you understand, navigate, and simplify the insurance approval process
- Downloadable materials, such as a sample letter of medical necessity and a sample letter of appeal, are available to help you support timely patient access

Visit the Deciphera AccessPoint website for information about our programs and downloadable resources: www.decipheraaccesspoint.com/hcp/romvimza#forms-and-resources

SELECT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

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.

Please see additional Safety Information throughout.

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For assistance with access issues, reach out to Deciphera AccessPoint™

Contact us via web, phone, or email.

- Use your browser to visit decipheraaccesspoint.com/hcp
- Call our dedicated Case Managers at 1-833-4DACCES (1-833-432-2237), Monday–Friday 8AM–8PM ET
- Email info@decipheraaccesspoint.com to schedule a call back

Use this QR code to visit the website

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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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