

## DRUG POLICY

---

# Romvimza™(vimseltinib)

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-Approved Indications

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

## POLICY

### Criteria for Initial Approval

#### **Tenosynovial Giant Cell Tumor (TGCT)**

Authorization of 12 months may be granted for the treatment of tenosynovial giant cell tumor (TGCT) with measurable disease (a lesion of at least 2 centimeters) for members who are not candidates for surgical resection.

### Continuation of Therapy

#### **Tenosynovial Giant Cell Tumor (TGCT)**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the Criteria for Initial Approval section when there is clinical benefit (e.g., decreased tumor volume score, improvement in range of motion of the affected joint or improvement of pain scores) and no evidence of unacceptable toxicity while on the current regimen.

### Other

Romvimza (vimseltinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

#### Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

#### Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Romvimza (vimseltinib) 14 mg capsules	1 carton (8 capsules) per 28 days	Recommended Dose: 30 mg orally twice weekly
Romvimza (vimseltinib) 20 mg capsules	1 carton (8 capsules) per 28 days	Dose adjustments are recommended for adverse reactions or hepatotoxicity: <ul style="list-style-type: none"><li>• 20 mg twice weekly – first dose reduction</li><li>• 14 mg twice weekly – second dose reduction</li></ul>
Romvimza (vimseltinib) 30 mg capsules	1 carton (8 capsules) per 28 days	

## PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

## REFERENCES

Romvimza [package insert]. Waltham, MA: Deciphera Pharmaceuticals, LLC.; February 2025.

Gelderblom H, Bhadri V, Stacchiotti S, et al. Vimseltinib versus placebo for tenosynovial giant cell tumour (MOTION): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2024;403(10445):2709-2719. doi: 10.1016/S0140-6736(24)00885-7

Gouin F and Noailles T. Localized and diffuse forms of tenosynovial giant cell tumor (formerly giant cell tumor of the tendon sheath and pigmented villonodular synovitis). *Orthop Traumatol Surg Res*. 2017;103(1S):S91-S97. doi: 10.1016/j.otsr.2016.11.002

Tap W, Sharma M, Vallee M, et al. The MOTION study: a randomized, phase III study of vimseltinib for the treatment of tenosynovial giant cell tumor. *Future Oncol*. 2024; 20(10):593-601. doi: 10.2217/fon-2023-0238

## POLICY HISTORY

**Policy #:** 05.05.86

**Original Effective Date:** July 24, 2025

**Reviewed:** August 2025

**Revised:**

**Current Effective Date:** July 24, 2025