HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Romvimza (vimseltinib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Romvimza, approved by the FDA in 2025, 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. Romvimza is a selective oral inhibitor of the colony-stimulating factor 1 receptor (CSF1R). It works by blocking CSF1R-driven signaling involved in the proliferation and accumulation of tumor-associated macrophages in TGCT.
TGCT is a rare, typically non-malignant tumor of the synovium, tendon sheath, and bursae that can lead to joint damage, pain, swelling, and functional impairment. Surgical resection remains the first-line treatment for TGCT, but in patients for whom surgery is not feasible or would result in significant morbidity, systemic treatment such as Romvimza may be considered.

Romvimza (vimseltinib) will be considered for coverage when the following criteria are met:

Tenosynovial Giant Cell Tumor (TGCT)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an oncologist or orthopedic surgeon; AND
3. Member has a documented diagnosis of benign TGCT confirmed by imaging (MRI) or histology; AND
4. Member is symptomatic (i.e., pain or stiffness); AND
5. Prescriber attests that surgical resection will potentially cause worsening functional limitation or severe morbidity; AND
6. Chart notes must document that baseline liver tests have been or will be completed prior to starting therapy.
7. **Dosage allowed/Quantity limit:**
   a) 30 mg orally twice weekly with at least 72 hours between doses.
   b) Quantity Limit: 8 capsules per 28 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improvement or stabilized signs and symptoms of disease (such as decreased pain and stiffness, increased range of motion, or reduced tumor volume).

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Romvimza (vimseltinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/7/2025	New policy for Romvimza created.

References:

1. Romvimza (vimseltinib) [package insert]. Deciphera Pharmaceuticals, LLC; February 2025.
2. IPD Analytics. Solid Tumors - Non Malignant. Available from: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Page/cd33496c-1413-40a5-8489-cbfb6c1ebbc6#comment-groups. Accessed April 7, 2025.
3. Tap WD, Sharma MG, 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.
4. 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.
5. Stacchiotti S, Dürr HR, Schaefer IM, et al. Best clinical management of tenosynovial giant cell tumour (TGCT): A consensus paper from the community of experts. *Cancer Treat Rev*. 2023;112:102491. doi:10.1016/j.ctrv.2022.102491.
6. U.S. National Library of Medicine. Study of Vimseltinib for Tenosynovial Giant Cell Tumor (MOTION, NCT05059262). Available from: https://clinicaltrials.gov/study/NCT05059262?tab=results. Accessed April 7, 2025.
7. National Comprehensive Cancer Network. Soft Tissue Sarcoma (Version 1.2025). https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed April 9, 2025.

Effective date: 10/01/2025
Revised date: 04/07/2025