# Vimseltinib (ROMVIMZA)
# Criteria for Use
# June 2026

**VA Pharmacy Benefits Management Services and National Formulary Committee**

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

## Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for vimseltinib.

- ☐ Known severe allergy to FD&C Yellow No. 5 (tartrazine) and/or No. 6 (Sunset Yellow FCF)
- ☐ Baseline ALT, AST, total bilirubin above the upper limit of normal
- ☐ Active liver or biliary tract disease, including nonalcoholic steatohepatitis or cirrhosis
- ☐ Active or uncontrolled infection
- ☐ Unmanageable drug interaction
- ☐ Pregnancy
- ☐ Lactating

## Inclusion Criteria

All the following must be selected to meet criteria.

- ☐ Care provided by a VA / VA Community Care oncologist or locally designated expert
- ☐ Histologically confirmed diagnosis of symptomatic, nonmetastatic tenosynovial giant cell tumor (TGCT)
- ☐ TGCT is not amenable to improvement with surgery or surgical resection likely to cause worsening functional limitation or severe morbidity
- ☐ No improvement after 12 weeks of **imatinib**; disease progression on imatinib or imatinib is medically inadvisable (i.e. contraindication, unmanageable toxicity, etc.)^

^ Prior imatinib permitted in MOTION; subgroup analysis indicates vimseltinib ORR 47% post-imatinib

## Additional Inclusion Criteria – Select If Applicable

- ☐ For females who can become pregnant: Pregnancy should be excluded prior to receiving vimseltinib.
- ☐ For females who can become pregnant and males with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 1 month after stopping treatment.
- ☐ For females who are lactating / providing breastmilk to an infant: Advise not to breastfeed during therapy and for 1 month after stopping treatment.

## Other Justification

- ☐ _____

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