CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL POLICY

Vimseltinib (Romvimza®)

Version: 1.0

EFFECTIVE DATE: 8/28/2025

NantHealth® | Eviti®

Please note the following:

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For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Vimseltinib (Romvimza®)

Discussion

Vimseltinib 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.[1]

Vimseltinib binds to the CSF1R at the switch control region, which regulates the kinase's conformational activation. This binding forces the receptor into an inactive state by stabilizing the inhibitory conformation. It prevents the phosphorylation of CSF1R, which is necessary for its activation. This inhibition blocks the signaling pathways that would normally be triggered by the CSF1 ligand. By inhibiting CSF1R, vimseltinib reduces the proliferation of cells that express CSF1R, such as macrophages and osteoclasts. This leads to decreased tumor growth and bone degradation.[2]

The most common adverse reactions include laboratory abnormalities such as increased AST, periorbital edema, fatigue, rash, increased cholesterol, peripheral edema, face edema, decreased neutrophils, decreased leukocytes, pruritus, and increased ALT. Clinically significant adverse reaction includes hepatotoxicity.

Vimseltinib is approved by the Food and Drug Administration (FDA) for tenosynovial giant cell tumor.[1] The National Comprehensive Cancer Network (NCCN) endorses vimseltinib for soft tissue sarcoma.[3]

Definitions

- **Colony-Stimulating Factor 1 Receptor (CSF1R) -** A protein that plays a crucial role in the regulation of the survival, proliferation, and differentiation of mononuclear phagocytic cells, which include macrophages and their precursors. It is a receptor tyrosine kinase that, upon binding its ligand CSF1, activates signaling pathways essential for the development and function of these immune cells.[4]
- **Food and Drug Administration (FDA)** - The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.[5]
- **National Comprehensive Cancer Network (NCCN)** - An alliance of more than 30 leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.[6]

Policy

Coverage will be considered for FDA approved indications and for NCCN category 1, 2A, or 2B recommendations when the following criteria are met:

Soft Tissue Sarcoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND

For **FDA** required criteria coverage:

3. Symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity;[1] OR

For **NCCN** required criteria coverage:

4. Single-agent therapy for the treatment of pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT).[3]

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Coding (CPT®, ICD-10, and HCPCS)

Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

Code	Description
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
J8999	Prescription drug, oral, chemotherapeutic, not otherwise specified

Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	8/28/2025
2	Policy Annual Review Dates:	
3	Department Owner:	Medical Affairs
4	NH Advisory Committee Approval Dates:	8/28/2025

5	Revision Changes:	

References

[1] Romvimza (Vimseltinib) [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219304s000lbl.pdf. Accessed June 2, 2025.

[2] Smith BD, Kaufman MD, Wise SC, et al. Vimseltinib: A Precision CSF1R Therapy for Tenosynovial Giant Cell Tumors and Diseases Promoted by Macrophages. Mol Cancer Ther. 2021;20(11):2098-2109. https://pmc.ncbi.nlm.nih.gov/articles/PMC9398179/. Accessed June 2, 2025.

[3] National Comprehensive Cancer Network. NCCN Guidelines: Soft Tissue Sarcoma. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed June 13, 2025.

[4] Lin CC. Clinical Development of Colony-Stimulating Factor 1 Receptor (CSF1R) Inhibitors. J Immunother Precis Oncol. 2021;4(2):105-114. Published 2021 May 14. https://pmc.ncbi.nlm.nih.gov/articles/PMC9153255/. Accessed June 2, 2025.

[5] U.S. Food & Drug Administration. https://www.fda.gov/about-fda/what-we-do. Accessed June 2, 2025.

[6] National Comprehensive Cancer Network. https://www.nccn.org/home. Accessed June 2, 2025.