

SPECIALTY GUIDELINE MANAGEMENT

MEKINIST (trametinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Mekinist is indicated, as a single agent or in combination with dabrafenib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
2. Mekinist is indicated, in combination with dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test.

Limitation of Use: Mekinist is not indicated for treatment of patients with melanoma who have progressed on prior BRAF-inhibitor therapy.

B. Compendial Uses

Melanoma, BRAF V600 activating mutation-positive

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Melanoma**

Authorization of 12 months may be granted for treatment of melanoma with a BRAF V600 activating mutation (e.g., BRAF V600E or BRAF V600K mutation).

B. **Non-Small Cell Lung Cancer (NSCLC)**

Authorization of 12 months may be granted for treatment of BRAF V600E mutation-positive NSCLC.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Mekinist [package insert]. East Hanover, NJ: Novartis Pharmaceutical Corporation; June 2017.
2. The NCCN Drugs & Biologics Compendium® ©2017 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed March 18, 2017.
3. The NCCN Clinical Practice Guidelines in Oncology™ Melanoma (Version 1.2017). ©2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 17, 2017.

4. The NCCN Clinical Practice Guidelines in Oncology™ Non-Small Cell Lung Cancer (Version 4.2017). ©2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 17, 2017.