



# 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

- 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 FDAapproved 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.

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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.