Clinical Policy: Trametinib (Mekinist)

Reference Number: PA.CP.PHAR.240
Effective Date: 01/18
Last Review Date: 04/18 Revision Log

Description
Trametinib (Mekinist®) is a kinase inhibitor.

FDA approved indication
Mekinist is indicated:

- As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test
- 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
  - 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 received prior BRAF-inhibitor therapy.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Mekinist is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Melanoma (must meet all)**:**
1. Diagnosis of unresectable or metastatic melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Presence of a BRAF V600E or BRAF V600K mutation as detected by an FDA approved test;
5. Dose does not exceed one 2 mg tablet per day.

Approval duration: 6 months

B. Non-small cell lung cancer (must meet all)**:**
1. Diagnosis of metastatic or recurrent non-small cell lung cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Presence of a BRAF V600E mutation as detected by an FDA approved test;
5. Mekinist will be used in combination with dabrafenib (Tafinlar);
6. Dose does not exceed 2 mg tablet per day.

Approval duration: 12 months

C. Other diagnoses/indications
1. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed one 2 mg tablet per day.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BRAF: B-Raf proto-oncogene serine/threonine kinase
ERK: extracellular signal-related kinase
FDA: Food and Drug Administration
LVEF: left ventricular ejection fraction
LLN: lower limit of normal
MEK: mitogen-activated extracellular signal-regulated kinase
NSCLC: non-small cell lung cancer

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Unresectable or metastatic melanoma with BRAF V600E or V600K mutations	2 mg orally once daily at least 1 hour before or at least 2 hours after a meal	2 mg/day
NSCLC	2 mg orally once daily at least 1 hour before or at least 2 hours after a meal	2 mg/day

VI. Product Availability

Tablets: 0.5 mg, 2 mg

VII. References

1. Mekinist Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2017. Available at www.pharma.us.novartis.com/product/pi/pdf/mekinist.pdf. Accessed June 30, 2017.
2. Trametinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed May 16, 2017.
3. Melanoma (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed May 16, 2017.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: added age; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; updated approval duration from 3/6 to 6/12 months; references reviewed and updated.	02.06.18	