

Clinical Policy: Trametinib (Mekinist)

Reference Number: CP.PHAR.240

Effective Date: 07/16

Last Review Date: 07/17

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation[®] 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. Presence of a BRAF V600E or BRAF V600K mutation as detected by an FDA approved test;
3. Mekinist will be used in one of the following ways:
 - a. As a single agent;
 - b. In combination with dabrafenib (Tafinlar);
4. Dose does not exceed one 2 mg tablet per day.

Approval duration: 3 months

B. Non-small cell lung cancer (must meet all):

1. Diagnosis of metastatic or recurrent non-small cell lung cancer;
2. Presence of a BRAF V600E mutation as detected by an FDA approved test;

3. Mekinist will be used in combination with dabrafenib (Tafinlar);
4. Dose does not exceed 2 mg tablet per day.

Approval duration: 3 months

C. Other diagnoses/indications

1. Refer to 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 Centene benefit or member has previously met initial approval criteria;
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: 6 months

B. Other diagnoses/indications (1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to 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 – 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 | LLN: lower limit of normal |
| ERK: extracellular signal-related kinase | MEK: mitogen-activated extracellular signal-regulated kinase |
| FDA: Food and Drug Administration | NSCLC: non-small cell lung cancer |
| LVEF: left ventricular ejection fraction | |

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 |
|---|-------|---------------|
| Policy split from CP.PHAR.117.Mekinist and Tafinlar and converted to new template. No generics available. Age requirement removed. NCCN compendial uses for melanoma are covered within the scope of the FDA approved uses; the remaining NCCN uses for NSCLC are added. | 06/16 | 07/16 |
| Safety criteria is revised according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Removed the following for initial criteria: disease has not progressed on prior BRAF-inhibitor therapy (e.g., Zelboraf, Tafinlar), if prior BRAF-inhibitor therapy was used. Added criteria for new FDA approved indication NSCLC. | 06/17 | 07/17 |

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in 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.

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