

Mekinist® (trametinib) (Oral)

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I. Length of Authorization

Coverage is provided for six months and may be renewed.

Coverage for the adjuvant treatment of melanoma is up to a maximum of 1 year of therapy.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Mekinist 0.5 mg tablet: 3 tablets per day
- Mekinist 2 mg tablet: 1 tablet per day

B. Max Units (per dose and over time) [Medical Benefit]:

- 2 mg daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Baseline left ventricular ejection fraction (LVEF) within normal limits; **AND**
- Patient is at least 18 years or older; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib, etc.) unless otherwise specified; **AND**

Melanoma †

- Patient has BRAF V600E or V600K mutation detected by FDA approved test*; **AND**
 - Used in combination with dabrafenib as adjuvant therapy for patients with lymph node involvement, following complete resection; **OR**
 - Used as a single-agent therapy in BRAF-inhibitor treatment-naïve patients with unresectable or metastatic disease; **OR**
 - Used in combination with dabrafenib in patients with unresectable or metastatic disease; **AND**

- Used as initial or subsequent therapy; **OR**
- Used as re-induction therapy for progression/relapse in patients who had disease control (i.e., complete response, partial response, or stable disease with no residual toxicity) for >3 months after previous therapy with trametinib ‡; **OR**
- Used as single agent for treatment of unresectable or metastatic Uveal Melanoma ‡

Anaplastic Thyroid Cancer (ATC) †

- Patient has BRAF V600E mutation detected by FDA approved test*; **AND**
- Used in combination with dabrafenib; **AND**
- Used for locally advanced or metastatic disease with no satisfactory locoregional treatment options

Non-Small Cell Lung Cancer †

- Patient has BRAF V600E mutation as detected by FDA approved test*; **AND**
- Patient has recurrent, advanced or metastatic disease; **AND**
- Used in combination with dabrafenib

Central Nervous System Cancers – Brain Metastases ‡

- Patient's primary cancer is BRAF V600E or V600K mutation positive melanoma; **AND**
- Used in combination with dabrafenib; **AND**
 - Patient has newly diagnosed or stable systemic disease or reasonable systemic treatment options; **OR**
 - Patient has recurrent brain metastases.

Colorectal Cancer (CRC) ‡

- Patient has BRAF V600E mutation as detected by FDA approved test*; **AND**
- Patient has progression of unresectable advanced or metastatic disease; **AND**
- Used as subsequent therapy; **AND**
 - Used in combination with dabrafenib; **AND**
 - Used in combination with cetuximab or panitumumab; **AND**
- Patient was previously treated with one of the following:
 - An oxaliplatin- or irinotecan- based therapy; **OR**
 - A fluoropyrimidine based therapy without irinotecan or oxaliplatin followed by FOLFOX or CapeOX without bevacizumab

*<http://www.fda.gov/CompanionDiagnostics>

† FDA Approved Indication(s); ‡ Compendia Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in Section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: interstitial lung disease/pneumonitis; cardiomyopathy; cutaneous/non-cutaneous malignancies; severe hemorrhagic events; colitis/gastrointestinal perforation; venous thromboembolism; persistent retinal pigment epithelial detachment (RPED); retinal vein occlusion (RVO); skin toxicity; serious febrile reactions; hyperglycemia; etc. **AND**
- Left ventricular ejection fraction (LVEF) has not had an absolute decrease from baseline \geq 10% and is not below the lower limit of normal (LLN)

Adjuvant treatment of Melanoma

- Treatment has not exceeded 1 year of therapy

Melanoma (metastatic or unresectable disease)

- Patient has completed initial induction; **AND**
- Used as re-induction therapy in patients who experienced disease control, but subsequently disease progression/relapse > 3 months after treatment discontinuation

V. Dosage/Administration

Indication	Dose
All indications	2 mg orally once daily taken until disease progression/recurrence or unacceptable toxicity (<i>for adjuvant treatment of melanoma treat until disease recurrence or unacceptable toxicity for up to 1 year</i>).

VI. Billing Code/Availability Information

HCPCS code:

- J8999 – Prescription drug oral, chemotherapeutic, Not Otherwise Specified
- C9399 – Unclassified drug or biological (Hospital Outpatient Use Only)

NDC:

- Mekinist 0.5 mg tablet: 00078-0666-xx
- Mekinist 2 mg tablet: 00078-0668-xx

VII. References

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10. Falchook GS, Lewis KD, Infante JR, et al. Activity of the MEK Inhibitor Trametinib (GSK1120212) in Advanced Melanoma in a Phase I, Dose-escalation Trial. The lancet oncology. 2012;13(8):782-789. doi:10.1016/S1470-2045(12)70269-3.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C17.0	Malignant neoplasm duodenum
C17.1	Malignant neoplasm jejunum

MEKINIST® (trametinib) Prior Auth Criteria

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ICD-10	ICD-10 Description
C17.2	Malignant neoplasm ileum
C17.8	Malignant neoplasm of overlapping sites of small intestines
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of large intestines
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C43.0	Malignant melanoma of lip

ICD-10	ICD-10 Description
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit
C73	Malignant neoplasm of thyroid gland
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung

ICD-10	ICD-10 Description
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C79.31	Secondary malignant neoplasm of brain
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.820	Personal history of malignant melanoma of skin

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC