Generic Name: Trametinib

Therapeutic Class or Brand Name: Mekinist

Applicable Drugs (if Therapeutic Class): Kinase Inhibitor

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/18/2018

Date Last Reviewed / Revised: 6/2/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following conditions A through F and must meet criteria listed under each applicable diagnosis.

A. Unresectable or metastatic melanoma

i. BRAF V600E or V600K mutations as detected by an FDA-approved test.

ii. Mekinist will be used as a single agent or in combination with Tafinlar (dabrafenib).

iii. Minimum age requirement: 18 years old.

B. Adjuvant treatment of melanoma with lymph node involvement following complete resection

i. BRAF V600E or V600K mutations as detected by an FDA-approved test.

ii. Mekinist will be used in combination with Tafinlar (dabrafenib).

iii. Minimum age requirement: 18 years old.

C. Advanced or metastatic non-small cell lung cancer (NSCLC)

i. BRAF V600E mutation as detected by an FDA-approved test.

ii. Mekinist will be used in combination with Tafinlar (dabrafenib).

iii. Minimum age requirement: 18 years old.

D. Locally advanced or metastatic anaplastic thyroid cancer (ATC)

i. BRAF V600E mutation as detected by an FDA-approved test.

ii. Documentation that there are no satisfactory locoregional treatment options.

iii. Mekinist will be used in combination with Tafinlar (dabrafenib).

iv. Minimum age requirement: 18 years old.

E. Unresectable or metastatic solid tumors

i. BRAF V600E mutation.

ii. Documentation of progression after prior treatment and no satisfactory alternative treatment options.

iii. Minimum age requirement: 1 year old.

F. Low-grade glioma
   i. BRAF V600E mutation.
   ii. Mekinist will be used in combination with Tafinlar (dabrafenib).
   iii. Documentation that systemic therapy is required.
   iv. Minimum age requirement: 1 year old.

II. If the request is for tablet formulation, body weight of at least 26 kg.

III. Treatment must be prescribed by or in consultation with an oncologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Treatment of melanoma after progression on BRAF inhibitors: Zelboraf (Vemurafenib) or Tafinlar (dabrafenib).
- Treatment of colorectal cancer.

OTHER CRITERIA

- Solid tumor uses per National Comprehensive Cancer Network (NCCN) guidelines:
  - Brain metastases from melanoma
  - Distant metastatic uveal melanoma
  - Central Nervous system cancers (eg, glioma, meningioma, astrocytoma, etc)
  - Follicular cancer
  - Hepatobiliary cancers (ie, gallbladder or cholangiocarcinoma)
  - Hürthle cell cancer
  - Low-grade serous ovarian cancer, fallopian tube cancer, primary peritoneal cancer
  - Papillary cancer
  - Occult Primary
  - Histiocytic Neoplasms (i.e., Langerhans Cell Histiocytosis (LCH), Erdheim-Chester Disease (ECD), Rosai-Dorfman Disease (RDD)
  - Adenocarcinomas
  - Salivary gland tumors

Quantity / Days Supply Restrictions

- Unresectable or metastatic melanoma: 2 mg once daily per 30 days
- Adjuvant treatment of melanoma: 2 mg once daily per 30 days, for up to 1 year
- NSCLC or ATC: 2 mg once daily per 30 days
- Unresectable or metastatic solid tumors: 2 mg once daily per 30 days
- LGG: 2 mg once daily per 30 days

Approval Length

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and the medication is effective. Please note: for adjuvant treatment of melanoma, Mekinist is only indicated to be given up to 1 year.

Appendix

- N/A

References

1. Mekinist. [Prescribing Information], East Hanover, NJ; Novartis Pharmaceuticals Corp; 2025. Accessed May 2, 2025. https://www.novartis.com/us-en/sites/novartis_us/files/mekinist.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Melanoma: Cutaneous. Version 2.2025. Updated January 28, 2025. Accessed May 2, 2025. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell Lunger Cancer. Version 3.2025. Updated January 14, 2025. Accessed May 2, 2025. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. Version 1.2025. Updated March 27, 2025. Accessed May 2, 2025. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf.
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 5.2024. Updated March 18, 2025. Accessed May 2, 2025. https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf