MEDICATION POLICY:
Mekinist®

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: 12/2/2023

PRIOR AUTHORIZATION CRITERIA

(may be considered medically necessary when criteria I through IV are met)

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

A. Unresectable or metastatic melanoma

1. Documentation of BRAF V600E or V600K mutations.
2. Mekinist will be used as a single agent or in combination with Tafinlar (dabrafenib).
3. Minimum age requirement: 18 years old.

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

1. Documentation of BRAF V600E or V600K mutations.
2. Mekinist will be used in combination with Tafinlar (dabrafenib).
3. Minimum age requirement: 18 years old.

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

1. Documentation of BRAF V600E mutation.
2. Mekinist will be used in combination with Tafinlar (dabrafenib).
3. Minimum age requirement: 18 years old.

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

1. Documentation of BRAF V600E mutation.
2. Documentation that there are no satisfactory locoregional treatment options.
3. Mekinist will be used in combination with Tafinlar (dabrafenib).
4. Minimum age requirement: 18 years old.

E. Unresectable or metastatic solid tumors

1. Documentation of BRAF V600E mutation
2. Documentation of progression after prior treatment and no satisfactory alternative treatment options.
3. Minimum age requirement: 1 years old.

F. Low-grade glioma
    1. Documentation of BRAF V600E mutation.
    2. Mekinist will be used in combination with Tafinlar (dabrafenib).
    3. Documentation that systemic therapy is required.
    4. Minimum age requirement: 1 years old.

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

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

IV. 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

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Unresectable or metastatic melanoma: total dose of 2 mg per day/30 days
- Adjuvant treatment of melanoma: total dose of 2 mg per day/30 days for up to 1 year
- NSCLC or ATC: total dose of 2 mg per day/30 days
- Unresectable or metastatic solid tumors: total dose of 2 mg per day/30 days

- LGG: total dose of 2 mg per day/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. Novartis Pharmaceuticals Corp; 2023. Accessed December 2, 2023. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/mekinist.pdf.
2. NCCN Clinical Practice Guidelines in Oncology. Melanoma: cutaneous. V.3.2023. Updated October 27,2023. Accessed December 2, 2023. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf
3. NCCN Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. V.5.2023. Updated November 8, 2023. Accessed December 2, 2023. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
4. NCCN Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. V.3.2022. Updated November 1, 2022. Accessed December 2, 2023. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf.
5. NCCN Clinical Practice Guidelines in Oncology. Central nervous system cancers. V.1.2023. Updated March 24, 2023. Accessed December 2, 2023. https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf