PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Mekinist Prior Authorization Policy
- Mekinist™ (trametinib tablets – GlaxoSmithKline)

REVIEW DATE: 07/15/2020

OVERVIEW

Mekinist, a kinase inhibitor, is indicated for the treatment of patients with the following conditions:[1]

- **Melanoma**, in the following situations:
  - As a single agent for unresectable or metastatic disease with a BRAF V600E or V600K mutation as detected by an FDA-approved test; AND
  - In combination with Tafinlar® (dabrafenib tablets), for treatment of unresectable or metastatic disease with a BRAF V600E or V600K mutation as detected by an FDA-approved test; AND
  - In combination with Tafinlar for adjuvant treatment of patients with a BRAF V600E or V600K mutation as detected by an FDA-approved test, and involvement of lymph nodes, following complete resection.
- **Non-small cell lung cancer**, in combination with Tafinlar, for treatment of disease that has the BRAF V600E mutation as detected by an FDA-approved test.
- **Thyroid cancer**, in combination with Tafinlar, for treatment of patients with locally advanced or metastatic anaplastic disease with BRAF V600E mutation and with no satisfactory locoregional treatment options.

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines support use of Mekinst in multiple cancers.

- **Melanoma:** Guidelines (version 3.2020 – May 18, 2020) recommend BRAF/MEK inhibitor combinations for first-line (preferred if clinically needed for early response) and subsequent treatment of metastatic or unresectable melanoma with a *V600* activating mutation.[2] While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor (Tafinlar or Zelboraf® [vemurafenib tablets]) is a recommended option, particularly if the patient is not a candidate for checkpoint immunotherapy. Following resection of limited metastatic disease with a *BRAF V600*-activating mutation, BRAF/MEK combination therapy is among the treatment options for patients with no evidence of disease. Tafinlar + Mekinist® (trametinib tablets) is also recommended in guidelines as adjuvant therapy (including for nodal recurrence) in some patients with Stage III disease, including use post-surgery or use after complete lymph node dissection. If unacceptable toxicity to Tafinlar/Mekinist, other BRAF/MEK combinations can be considered. NCCN guidelines for uveal melanoma (version 1.2020 – May 21, 2020) list Mekinist as a treatment option for distant metastatic disease.[3]
- **NSCLC:** Guidelines (version 6.2020 – June 25, 2020) list Tafinlar + Mekinist among the first-line therapy and subsequent therapy options for tumors with a *BRAF* mutation.[4] NCCN also notes that monotherapy with a BRAF inhibitor (Tafinlar or Zelboraf) is a treatment option when combination therapy is not tolerated.
- **Thyroid Cancer:** Guidelines (version 1.2020 – June 12, 2020) list Tafinlar + Mekinist as a treatment option for metastatic anaplastic thyroid cancer with a *BRAF* mutation.[5] Tafinlar and Zelboraf are also treatment options for the treatment of iodine-refractory differentiated thyroid cancer (follicular, Hürthle cell, and papillary cancer subtypes) with a *BRAF V600* mutation.

- **Ovarian, Including Fallopian Tube and Primary Peritoneal Cancer:** Guidelines (version 1.2020 – March 11, 2020) recommend Mekinist among the targeted therapy options for recurrent low-grade serous disease.[6]

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Mekinist. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Mekinist is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Melanoma.** Approve for 3 years if the patient meets BOTH of the following (A and B):
   A) Patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma; AND
   Note: This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery.
   B) Patient has *BRAF V600* mutation-positive disease.

2. **Non-Small Cell Lung Cancer.** Approve for 3 years if the patient meets BOTH of the following (A and B):
   A) Patient has *BRAF V600E* mutation-positive disease; AND
   B) The agent is being used in combination with Tafinlar (dabrafenib capsules).

3. **Thyroid Cancer, Anaplastic.** Approve for 3 years if the patient meets ALL of the following (A, B, and C):
   A) Patient has locally advanced or metastatic anaplastic disease; AND
   B) Mekinist will be taken in combination with Tafinlar, unless intolerant; AND
   C) Patient has *BRAF V600* mutation-positive disease.

Other Uses with Supportive Evidence

4. **Ovarian/Fallopian Tube/Primary Peritoneal Cancer**. Approve for 3 years if the patient meets the following criteria (A and B):
   A) Patient has recurrent disease; AND
   B) The medication is used for low-grade serous carcinoma.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Mekinist is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Mekinist® tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; June 2020.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (Version 3.2020 – May 18, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 2, 2020.
3. The NCCN Uveal Melanoma Clinical Practice Guidelines in Oncology (Version 1.2020 – May 21, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 2, 2020.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 6.2020 – June 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 2, 2020.
5. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (Version 1.2020 – June 12, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 2, 2020.
6. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (Version 1.2020 – March 11, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 2, 2020.