Reference number(s)
1681-A

SPECIALTY GUIDELINE MANAGEMENT

MEKINIST (trametinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Mekinist is indicated, as a single agent in BRAF-inhibitor treatment-naïve patients or 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.
2. Mekinist is indicated, in combination with dabrafenib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection.
3. Mekinist is indicated, in combination with dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test.
4. Mekinist is indicated, in combination with dabrafenib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and no satisfactory locoregional treatment options.

B. Compendial Uses
1. Melanoma (including brain metastases), BRAF V600 activating mutation-positive
2. Glioma, BRAF V600 activating mutation-positive
3. Meningioma, BRAF V600 activating mutation-positive
4. Astrocytoma, BRAF V600 activating mutation-positive
5. Uveal melanoma as a single agent
6. Colorectal cancer, BRAF V600E activating mutation-positive
7. Brain cancer with neurofibromatosis type 1

All other indications are considered experimental/investigational and are not a covered benefit.

II. DOCUMENTATION

Submission of BRAF mutation documentation is necessary to initiate the prior authorization review for applicable indications as outlined in section III.

III. CRITERIA FOR INITIAL APPROVAL

A. Melanoma
1. Authorization of 12 months may be granted for treatment of unresectable or metastatic cutaneous melanoma with a BRAF V600 activating mutation as a single agent or in combination with dabrafenib (Tafinlar).

2. Authorization of 12 months may be granted for treatment of brain metastases from melanoma with a BRAF V600 activating mutation in combination with dabrafenib (Tafinlar).
3. Authorization of 12 months may be granted for adjuvant treatment of cutaneous melanoma with a BRAF V600 activating mutation in combination with dabrafenib (Tafinlar) following complete lymph node dissection/resection or recurrence.
4. Authorization of 12 months may be granted for treatment of metastatic uveal melanoma as a single agent.

B. Non-Small Cell Lung Cancer (NSCLC)
Authorization of 12 months may be granted for treatment of BRAF V600E mutation-positive recurrent, advanced, or metastatic NSCLC in combination with dabrafenib (Tafinlar).

C. Anaplastic Thyroid Cancer (ATC)
Authorization of 12 months may be granted for treatment of metastatic BRAF V600E mutation-positive ATC in combination with dabrafenib (Tafinlar).

D. Central Nervous System Cancer
Authorization of 12 months may be granted for treatment of central nervous system cancer in a member with either of the following:
1. BRAF V600 mutation-positive glioma, meningioma, or astrocytoma
2. Brain cancer and neurofibromatosis type 1

E. Colorectal Cancer
Authorization of 12 months may be granted for treatment of unresectable advanced or metastatic colorectal cancer when the following criteria are met:
1. Mekinist is used in combination with dabrafenib (Tafinlar) and either cetuximab or panitumumab
2. Tumor is positive for BRAF V600E mutation.
3. Will be used as subsequent therapy

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorizatoin for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. For patients using Mekinist for adjuvant treatment of cutaneous melanoma, only 12 months of therapy total will be approved.

V. REFERENCES

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9. Lassaletta, A, Guerreiro Stucklin, A, Ramaswamy, V, et al. Profound clinical and radiological response to BRAF inhibition in a 2-month-old diencephalic child with hypothalamic/chiasmatic glioma. *Pediatric Blood and Cancer*. 2016; 63: 2038-2041. doi:10.1002/pbc.26086.
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11. Knight T, Shatara M, Carvalho L, et al. Dramatic response to trametinib in a male child with neurofibromatosis type 1 and refractory astrocytoma. *Pediatr Blood Cancer*. 2019; 66(1):e27474.
12. See WL, Tan IL, Mukherjee J, et al. Sensitivity of Glioblastomas to Clinically Available MEK Inhibitors Is Defined by Neurofibromin 1 Deficiency. *Cancer Res*. 2012;72(13):3350.