Mekinist (trametinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Mekinist (trametinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Mekinist (trametinib) may be approved if the following criteria are met:

I. Individual has a diagnosis of Central Nervous System (CNS) Cancer (NCCN 2A); **AND**
   A. Individual is using in combination with dabrafenib for one of the following:
      1. Individual has a primary diagnosis of melanoma and disease has metastasized to the brain; **OR**
      2. Individual is using as adjuvant therapy for primary CNS cancer; **OR**
      3. Individual is using for Adult Circumscribed Glioma; **OR**
      4. Individual is using for recurrent or progressive Adult Glioma Glioblastoma; **OR**
      5. Individual has relapsed or refractory pediatric diffuse high-grade gliomas;

   AND
   B. Individual has BRAF V600E mutation;

OR

II. Individual has a diagnosis of low-grade glioma (LGG) (Label); **AND**
   A. Individual is 1 year of age and older; **AND**
   B. Individual is using in combination with dabrafenib; **AND**
   C. Individual requires systemic therapy; **AND**
   D. Individual has BRAF V600E mutation;

OR

III. Individual has a diagnosis of unresectable or metastatic Gastrointestinal Stromal Tumor (NCCN 2A); **AND**
   A. Individual is using in combination with dabrafenib; **AND**
   B. Individual has BRAF V600E;

OR

IV. Individual has a diagnosis of unresectable or metastatic Hepatobiliary Cancer (NCCN 2A); **AND**
   A. Individual is using in combination with dabrafenib; **AND**
   B. Individual has confirmed disease progression after systemic treatment; **AND**
   C. Individual has BRAF V600E mutation;

OR

V. Individual has a diagnosis of symptomatic and/or relapsed/refractory Histiocytic Neoplasm, including Erdheim-Chester Disease, Langerhans Cell Histiocytosis or Rosai-Dorfman Disease (NCCN 2A); **AND**
   A. Individual is using as monotherapy**; AND**
   B. Individual has mitogen-activated protein (MAP) kinase pathway mutation, or no detectable mutation, or testing not available;

OR

VI. Individual has a diagnosis of unresectable or metastatic malignant cutaneous Melanoma (Label, NCCN 1, 2A); **AND**
   A. Individual is using as monotherapy; **AND**
   B. Individual has not been previously treated with a BRAF inhibitor;

      OR

   C. Individual is using in combination with dabrafenib; **AND**
   D. Individual has either BRAF V600E or V600K mutation (or BRAF V600 activating mutation);

OR

VII. Individual has a diagnosis of cutaneous melanoma (Lable, NCCN 1, 2A); **AND**
   A. Individual is using in combination with dabrafenib; **AND**
   B. Individual is using as adjuvant treatment; **AND**
   C. Individual has disease involvement of lymph node(s), following complete resection or wide excision; **AND**
   D. Individual has either BRAF V600E or V600K mutation;

OR

VIII. Individual has a diagnosis of metastatic Non-Small Cell Lung Cancer (NSCLC) (Label, NCCN 2A); **AND**
   A. Individual is using in combination with dabrafenib; **AND**
   B. Individual has BRAF V600E mutation;

OR

IX. Individual has a diagnosis of ovarian cancer, low-grade serous carcinoma (NCCN 2A); **AND**
   A. Individual is using as a single-agent; **AND**
   B. Individual has platinum-sensitive or platinum-resistant recurrence to disease;

OR

X. Individual has a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) (Label, NCCN 2A); **AND**
   A. Individual is using in combination with dabrafenib; **AND**
   B. Individual has no satisfactory locoregional treatment options; **AND**
   C. Individual has BRAF V600E mutation;

OR

XI. Individual has a diagnosis of metastatic or unresectable Uveal Melanoma (NCCN 2A); **AND**

A. Individual is using as monotherapy;

OR

XII. Individual has a diagnosis of unresectable or metastatic solid tumors (Label, NCCN 2A); **AND**

A. Individual is 1 year of age and older; **AND**
B. Individual is using in combination with dabrafenib; **AND**
C. Individual has progressed following prior treatment and has no satisfactory alternative treatment options; **AND**
D. Individual has BRAF V600E mutation.

Mekinist (trametinib) may not be approved for the following:

I. Individual with colorectal cancer.

Key References:

1. Brown NF, Carter T, Kitchen N, Mulholland P. Dabrafenib and trametinib in BRAFV600E mutated glioma. CNS Oncol. 2017;6(4):291-296. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6004887/pdf/cns-06-291.pdf 2.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 5, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Gershenson DM, Miller A, et al. A randomized phase II/III study to assess the efficacy of trametinib in patients with recurrent or progressive low-grade serous ovarian or peritoneal cancer [abstract]. Ann Oncol. 2019;30 (suppl_5): abstr LBA61.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 5, 2022
    a. Ampullary Adenocarcinoma. V1.2023. Revised April 27, 2023.
    b. Biliary Tract Cancers. V2.2023. Revised May 10, 2023.
    c. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
    d. Cutaneous Melanoma. V2.2023. Revised March 10, 2023.
    e. Esophageal and Esophagogastric Junction Cancers. V2.2023. Revised March 10, 2023.
    f. Gastric Cancer. V1.2023. Revised March 10, 2023.
    g. Gastrointestinal Stromal Tumors. V1.2023. Revised March 13, 2023.
    h. Hepatobiliary Cancers. V1.2022. Revised March 29, 2022.
    i. Head and Neck Cancers. V2. 2023. Revised May 15, 2023.
    j. Histiocytic Neoplasms. V1.2022. Revised May 20, 2022.
    k. Neuroendocrine and Adrenal Tumors. V2. 2022. Revised December 21, 2022.
    l. Non-Small Cell Lung Cancer. V3.2023. Revised April 13, 2023.
    m. Ovarian Cancer. V2.2023. Revised June 2, 2023.
    n. Pancreatic Adenocarcinoma. V2.2023. Revised June 19, 2023.
    o. Pediatric Central Nervous System Cancers. V2.2023. Revised October 31, 2022.
    p. Thyroid Carcinoma. V2.2023. Revised May 18, 2023
8. Marks AM, Bindra RS, DiLuna ML, et al. Response to the BRAF/MEK inhibitors dabrafenib/trametinib in an adolescent with a BRAF V600E mutated anaplastic ganglioglioma intolerant to vemurafenib. Pediatr Blood Cancer. 2018;65(5):e26969

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