UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Mekinist

Program	Prior Authorization
Medication	Mekinist® (trametinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

1. Background:

Mekinist® (trametinib) is a kinase inhibitor indicated as a single agent or in combination with Tafinlar® (dabrafenib) for treatment of patients with unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutations as detected by an FDA-approved test. It is also indicated in combination with Tafinlar for the treatment of metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA approved test, for the adjuvant treatment of melanoma with BRAF V600E or BRAF V600K mutations involving the lymph nodes following resection and for the treatment of locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options. Mekinist is not indicated for treatment of patients with melanoma who have progressed on prior BRAF-inhibitor therapy.[1]

The National Comprehensive Cancer Network (NCCN) also recommends use of Mekinist in combination with Tafinlar for the adjuvant treatment of anaplastic thyroid cancer with BRAF V600E mutations following resection and for the treatment of central nervous system (CNS) cancer in patients with melanoma.[2]

Information on FDA-approved tests for the detection of BRAFV600 mutations in melanoma may be found at: http://www.fda.gov/CompanionDiagnostics.[1]

2. Coverage Criteria:

A. Melanoma

1. Initial Authorization

a. **Mekinist** will be approved based on **both** of the following criteria:

(1) **One** of the following:

(a) Unresectable melanoma
(b) Metastatic melanoma

(c) **Both** of the following:

i. Prescribed as adjuvant therapy for melanoma involving the lymph nodes
ii. Used in combination with Tafinlar (dabrafenib)

-AND-

(2) Cancer is positive for BRAF V600 mutation

Authorization will be issued for 12 months.

2. Reauthorization

a. **Mekinist** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Mekinist therapy

Authorization will be issued for 12 months.

B. Non-Small Cell Lung Cancer (NSCLC)

1. Initial Authorization

a. **Mekinist** will be approved based on **all** of the following criteria:

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Disease is **one** of the following:

(a) Metastatic
(b) Advanced
(c) Recurrent

-AND-

(3) Cancer is positive for BRAF V600E mutation

-AND-

(4) Used in combination with Tafinlar (dabrafenib)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Mekinist** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Mekinist therapy

Authorization will be issued for 12 months.

C. Thyroid Cancer

1. Initial Authorization

a. **Mekinist** will be approved based on **all** of the following criteria:

(1) Diagnosis of anaplastic thyroid cancer (ATC)

-AND-

(2) Cancer is positive for BRAF V600E mutation

-AND-

(3) Used in combination with Tafinlar (dabrafenib)

-AND-

(4) **One** of the following:

(a) Disease is **one** of the following:

i. Metastatic
ii. Locally advanced
iii. Unresectable

-OR-

(b) Prescribed as adjuvant therapy following resection

Authorization will be issued for 12 months.

2. Reauthorization

a. **Mekinist** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Mekinist therapy

Authorization will be issued for 12 months.

D. Central Nervous System (CNS) Cancers

1. Initial Authorization

a. **Mekinist** will be approved based on **all** of the following criteria:

(1) Patient has metastatic brain lesions

-AND-

(2) Mekinist is active against primary tumor (melanoma)

-AND-

(3) Used in combination with Tafinlar (dabrafenib)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Mekinist** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Mekinist therapy

Authorization will be issued for 12 months.

E. NCCN Recommended Regimens

1. Initial Authorization

a. **Mekinist** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Mekinist** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Mekinist therapy **Authorization will be issued for 12 months.**

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Mekinist [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available atwww.nccn.org. Accessed January 30, 2020.

Program	Prior Authorization - Mekinist (trametinib)
Change Control	
5/2016	New program
3/2017	Annual review. Updated references and template.
3/2018	Updated background information to include new indication in NSCLC with BRAF V600E mutation. Updated criteria to include NCCN recommendation of adjuvant treatment in combination with Tafinlar in stage III disease. Updated references. Added NCCN recommended regimen review criteria.
3/2019	Updated background and criteria to include new indications for the adjuvant treatment of melanoma with BRAF V600 mutation and NCCN recommendation for the treatment of ATC with BRAF V600 mutations. Updated references.
3/2020	Annual review. Updated references.