UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Mekinist

Program	Prior Authorization
Medication	Mekinist® (trametinib)
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

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 BRAFV600E mutation as detected by an FDA approved test.[1]

The National Comprehensive Cancer Network (NCCN) also recommends use of Mekinist in combination with Tafinlar for the adjuvant treatment of stage III melanoma with BRAF V600 mutations.[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 diagnoses:

(a) Unresectable melanoma
(b) Metastatic melanoma
(c) **Both** of the following:

i. Prescribed as adjuvant therapy for stage III melanoma
ii. Used in combination with Tafinlar (dabrafenib)

-AND-

(2) Cancer is BRAFV600 mutant type (MT)

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) Cancer is positive for BRAF V600E mutation

-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.

C. 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. <u>Reauthorization</u>

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. References:

1. Mekinist [package insert]. Research Triangle Park, NC:GlaxoSmithKline; June 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available atwww.nccn.org. Accessed January 12, 2018.

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.