MEDICATION POLICY

Generic Name: Trametinib

Therapeutic Class or Brand Name: Mekinist®

Applicable Drugs (if Therapeutic Class)**:** Kinase Inhibitor

Date of Origin: 5/18/2018 **Date Last Reviewed/Revised:** _____

GPI Code: 21533570100

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of one of the following conditions A through D and must meet criteria listed under each applicable diagnosis

A. Unresectable or metastatic melanoma and criterion 1 and 2 are met:

1. Documentation of BRAF V600E or V600K mutations as detected by and FDA approved test.
2. Mekinist® will be used as a single agent or in combination with Tafinlar® (dabrafenib)

B. Melanoma with lymph node involvement following complete resection and criterion 1 and 2 are met:

1. Documentation of BRAF V600E or V600K mutations as detected by an FDA approved test
2. Mekinist® will be used in combination with Teflinar®

C. Non-small cell lung cancer (NSCLC) and criterion 1 and 2 are met:

1. Documentation of BRAF V600E mutation as detected by an FDA approved test
2. Mekinist® will be used in combination with Teflinar®

D. Locally advanced or metastatic anaplastic thyroid cancer (ATC) and criterion 1 and 2 are met:

1. Documentation of BRAF V600E mutation as detected by and FDA approved test
2. Documentation that there are no satisfactory locoregional treatment options
3. Mekinist® will be used in combination with Teflinar®

II. Minimum age requirement: 18 years old

III. Prescribing physician is an oncologist

Exclusion Criteria:

- Disease progression of melanoma with prior BRAF inhibitors, Zelboraf (Vemurafenib),Tafinlar (dabrafenib)

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.

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Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Unresectable or metastatic melanoma - total dose of 2 mg per day/30 days
- Adjuvant treatment of melanoma- total dose of 2 mg per day/30 days for up to 1 year
- NSCLC or ATC- total dose of 2 mg per day/30 days

Approval Length:

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and the medication is effective. *Please note:* for adjuvant treatment of melanoma Mekinist is only indicated to be given up to 1 year.

Appendix:

N/A

References:

1. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/mekinist.pdf.
2. Medi-span
3. https://www.premera.com/medicalpolicies/5.01.534.pdf
4. https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru308reg.pdf.