TRAMETINIB

Generic	Brand	HICL	GCN	Exception/Other
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST	40361		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
   - The medication will be used as a single agent **OR** in combination with Tafinlar (dabrafenib)
   - The patient has not experienced disease progression while on prior BRAF inhibitor therapy (e.g., Zelboraf, Tafinlar)

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **2mg tablets (GPID 34727): #30 tablets per 30 days.**
   - **0.5mg tablets (GPID 34726): #90 tablets per 30 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient has BRAF V600E mutation as detected by an FDA-approved test
   - The medication will be used in combination with Tafinlar (dabrafenib)

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **2mg tablets (GPID 34727): #30 tablets per 30 days.**
   - **0.5mg tablets (GPID 34726): #90 tablets per 30 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of melanoma and meet **ALL** of the following criteria?
   - The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
   - The medication has not previously been used for more than one year
   - The medication will be used in combination with Tafinlar (dabrafenib) in the adjuvant setting
   - There is involvement of lymph node(s), following complete resection
   - The patient has not experienced disease progression while on prior BRAF inhibitor therapy (e.g., Zelboraf, Tafinlar)

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **2mg tablets (GPID 34727): #30 tablets per 30 days.**
   - **0.5mg tablets (GPID 34726): #90 tablets per 30 days.**

   If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) and meet **ALL** of the following criteria?
   - The patient has BRAF V600E mutation
   - The medication will be used in combination with Tafinlar (dabrafenib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **2mg tablets (GPID 34727): #30 tablets per 30 days.**
   - **0.5mg tablets (GPID 34726): #90 tablets per 30 days.**

   If no, do not approve.
   DENIAL TEXT: The guideline named **TRAMETINIB (Mekinist)** requires a diagnosis of unresectable or metastatic melanoma, metastatic non-small cell lung cancer (NSCLC), melanoma, or locally advanced or metastatic anaplastic thyroid cancer (ATC). In addition, the following criteria must be met:
   For diagnosis of unresectable or metastatic melanoma, approval requires:
   - The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
   - The medication will be used as a single agent **OR** in combination with Tafinlar (dabrafenib)
   - The patient has not experienced disease progression while on prior BRAF inhibitor therapy (e.g., Zelboraf, Tafinlar)

   For diagnosis of metastatic non-small cell lung cancer (NSCLC), approval requires:
   - The patient has BRAF V600E mutation as detected by an FDA-approved test
   - The medication will be used in combination with Tafinlar (dabrafenib)

   For diagnosis of melanoma, approval requires:
   - The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
   - The medication has not previously been used for more than one year
   - The medication will be used in combination with Tafinlar (dabrafenib) in the adjuvant setting
   - There is involvement of lymph node(s), following complete resection
   - The patient has not experienced disease progression while on prior BRAF inhibitor therapy (e.g., Zelboraf, Tafinlar)

   For diagnosis of locally advanced or metastatic anaplastic thyroid cancer, approval requires:
   - The patient has BRAF V600E mutation
   - The medication will be used in combination with Tafinlar (dabrafenib)
   - The patient has no satisfactory locoregional treatment options available

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RATIONALE
Ensure appropriate use of Mekinist based on FDA-approved indications and dosing.

FDA APPROVED INDICATIONS
- Mekinist is a kinase inhibitor indicated as a single agent 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
- Mekinist is used 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
- Mekinist is used 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
- Mekinist is used in combination with dabrafenib, for the treatment of patients with locally advanced or metastic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options

Limitation of use: Mekinist is not indicated for treatment of patients with melanoma who have progressed on prior BRAF-inhibitor therapy.

DOSAGE AND ADMINISTRATION
Confirm the presence of BRAF V600E or BRAF V600K mutation in tumor specimens prior to initiation of treatment with Mekinist and dabrafenib.

Unresectable or Metastatic Melanoma: The recommended dose is 2 mg orally taken once daily as a single agent or in combination with dabrafenib, until disease progression or unacceptable toxicity.

NSCLC: The recommended dose is 2 mg orally taken once daily in combination with dabrafenib, until disease recurrence or unacceptable toxicity.

Melanoma: The recommended dose is 2 mg orally taken once daily in combination with dabrafenib, until disease recurrence or unacceptable toxicity for up to 1 year.

Locally advanced or metastatic ATC: The recommended dose is 2 mg orally taken once daily in combination with dabrafenib, until disease recurrence or unacceptable toxicity.

Recommended Dose Reductions For Adverse Reactions Associated with MEKINIST

Action	Recommended Dosage
First Dose Reduction	1.5 mg orally once daily
Second Dose Reduction	1 mg orally once daily
Subsequent Modification	Permanently discontinue if unable to tolerate MEKINIST 1 mg orally once daily

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REFERENCES

- Mekinist [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/15/18

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