STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST	40361		GPI-10 (2153357010)	

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 a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - The requested medication will be used as a single agent in a BRAF-inhibitor treatment-naive patient OR in combination with Tafinlar (dabrafenib)

   If yes, continue to #7.
   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 a BRAF V600E mutation as detected by an FDA-approved test
   - The requested medication will be used in combination with Tafinlar (dabrafenib)

   If yes, continue to #7.
   If no, continue to #3.

3. Does the patient have a diagnosis of melanoma and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - The requested medication will be used as an adjuvant therapy in combination with Tafinlar (dabrafenib)
   - There is involvement of lymph node(s), following complete resection

   If yes, continue to #7.
   If no, continue to #4.

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 a BRAF V600E mutation
   - The requested medication will be used in combination with Tafinlar (dabrafenib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, continue to #7.
   If no, continue to #5.

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GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a BRAF V600E mutation
   - The requested medication will be used in combination with Tafinlar (dabrafenib)
   - The patient's disease has progressed following prior treatment and has no satisfactory alternative treatment options

   If yes, continue to #7.
   If no, continue to #6.

6. Does the patient have a diagnosis of low-grade glioma (LGG) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient has a BRAF V600E mutation
   - The requested medication will be used in combination with Tafinlar (dabrafenib)
   - The patient requires systemic therapy

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the request for the tablet formulation?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2mg: #1 per day.**
   - **0.5mg: #3 per day.**

   If no, continue to #8.

8. Is the request for the oral solution **AND** the patient meets the following criterion?
   - The patient is unable to swallow Mekinist (trametinib) tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #42mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRAMETINIB (Mekinist)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   3. Melanoma (a type of skin cancer)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (tumor that cannot be removed by surgery or has spread to other parts of the body)
   6. Low-grade glioma (LGG: a type of brain cancer)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer) OR in combination with Tafinlar (dabrafenib)

C. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You have a BRAF V600E mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)

D. **If you have melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   3. There is involvement of lymph node(s), following complete resection (surgical removal)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have a BRAF V600E mutation (abnormal change in gene)
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   3. You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

(Denial text continued on next page)

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

F. **If you have an unresectable or metastatic solid tumor, approval also requires:**
   1. You are 1 year of age or older
   2. You have a BRAF V600E mutation (abnormal change in gene)
   3. The requested medication will be used in combination with Tafinlar (dabrafenib)
   4. Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

G. **If you have low-grade glioma, approval also requires:**
   1. You are 1 to 17 years of age
   2. You have a BRAF V600E mutation (abnormal change in gene)
   3. The requested medication will be used in combination with Tafinlar (dabrafenib)
   4. You require systemic therapy (treatment that targets the entire body)

H. **If the request is for the oral solution, approval also requires:**
   1. You are unable to swallow Mekinist (trametinib) tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mekinist.

REFERENCES

- Mekinist [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
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P&T Approval: 10/23