STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMETINIB DIMETHYL SULFOXIDE

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

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

   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 requested medication will be used in combination with Tafinlar (dabrafenib)

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

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

   If no, continue to #4.

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TRAMETINIB DIMETHYL SULFOXIDE

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 or GPI-14 with the following quantity limits:**
   - **Mekinist 2mg: #1 tablet per day.**
   - **Mekinist 0.5mg: #3 tablets per day.**

   If no, do not approve.
   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 DIMETHYL SULFOXIDE (Mekinist)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Unresectable or metastatic melanoma (skin cancer that cannot be removed by surgery or has spread)
      2. Metastatic non-small cell lung cancer (NSCLC: lung cancer that has spread in body)
      3. Melanoma (skin cancer)
      4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: thyroid cancer that has spread in body)
   B. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You have BRAF V600E or V600K mutations (types of genes) as detected by a Food and Drug Administration (FDA)-approved test
      2. The requested medication will be used in combination with Tafinlar (dabrafenib) OR as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer)
   C. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
      1. You have BRAF V600E mutation (type of gene) as detected by an Food and Drug Administration -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 BRAF V600E or V600K mutations (types of genes) 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)

   (Denial text continued on next page)

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TRAMETINIB DIMETHYL SULFOXIDE

GUIDELINES FOR USE (CONTINUED)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer (ATC), approval also requires:**
   1. You have BRAF V600E mutation (type of gene mutation)
   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)

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; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/26/20
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