STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DABRAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DABRAFENIB MESYLATE	TAFINLAR	40360		GPI-10 (2153202510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ONE** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test AND the requested medication will be used as a single agent
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test AND the requested medication will be used in combination with Mekinist (trametinib)

   If yes, continue to #7.
   If no, continue to #2.

2. 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 has not previously been used for more than one year
   - The requested medication will be used in combination with Mekinist (trametinib) for adjuvant treatment
   - There is involvement of lymph node(s) following complete resection

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

3. 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 Mekinist (trametinib)

   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 Mekinist (trametinib)
   - The patient has no satisfactory locoregional treatment options available

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

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DABRAFENIB

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 Mekinist (trametinib)
   - The patient's disease has progressed following prior treatment and have 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 Mekinist (trametinib)
   - 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 capsule formulation?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, continue to #8.

8. Is the request for the tablet for oral suspension **AND** the patient meets the following criterion?
   - The patient cannot swallow Tafinlar (dabrafenib) capsules

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #30 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DABRAFENIB

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 **DABRAFENIB (Tafinlar)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   2. Melanoma (a type of skin cancer)
   3. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   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 it has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (tumor that cannot be completely 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 ONE of the following:**
   1. You have a BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used as a single agent (by itself)
   2. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used in combination with Mekinist (trametinib)

C. **If you have melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
   2. The requested medication has not previously been used for more than one year
   3. The requested medication will be used in combination with Mekinist (trametinib) for adjuvant (additional) treatment
   4. There is involvement of lymph node(s) following complete resection (removal by surgery)

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

(Denial text continued on next page)

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have a BRAF V600E mutation (type of gene mutation)
   2. The requested medication will be used in combination with Mekinist (trametinib)
   3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

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 (type of gene mutation)
   3. The requested medication will be used in combination with Mekinist (trametinib)
   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 (type of gene mutation)
   3. The requested medication will be used in combination with Mekinist (trametinib)
   4. You require systemic therapy (treatment that targets the entire body)

H. **If the request is for the tablet for oral suspension, approval also requires:**
   1. You cannot swallow Tafinlar (dabrafenib) capsules

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 Tafinlar.

REFERENCES

- Tafinlar [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