DABRAFENIB

Generic	Brand	HICL	GCN	Exception/Other
DABRAFENIB MESYLATE	TAFINLAR	40360		

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 mutation as detected by an FDA-approved test
   - The medication will be used as a single agent

   If yes, **approve for 12 months by HICL with a quantity limit of #120 capsules per 30 days.**
   If no, continue to #2.

2. 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 in combination with Mekinist (trametinib)

   If yes, **approve for 12 months by HICL with a quantity limit of #120 capsules 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 Mekinist (trametinib) for adjuvant treatment
   - There is involvement of lymph node(s) following complete resection

   If yes, **approve for 12 months by HICL with a quantity limit of #120 capsules per 30 days.**
   If no, continue to #4.

4. 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 Mekinist (trametinib)

   If yes, **approve for 12 months by HICL with a quantity limit of #120 capsules per 30 days.**
   If no, continue to #5.

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

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

   If yes, **approve for 12 months by HICL with a quantity limit of #120 capsules per 30 days.** If no, do not approve.
   DENIAL TEXT: The guideline named **DABRAFENIB (Tafinlar)** 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 mutation as detected by an FDA-approved test
   - The medication will be used as a single agent

   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 in combination with Mekinist (trametinib)

   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 Mekinist (trametinib) for adjuvant treatment
   - There is involvement of lymph node(s) following complete resection

   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 Mekinist (trametinib)

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

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DABRAFENIB

RATIONALE
Ensure appropriate use of Tafinlar (dabrafenib) based on FDA approved indications and dosing.

FDA APPROVED INDICATIONS
Tafinlar is a kinase inhibitor indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.

Tafinlar is indicated, in combination with Mekinist (trametinib) for:
- The treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
- 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.
- The treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test.
- The treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.

Limitation of Use: Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF NSCLC, or wild-type BRAF ATC.

DOSAGE AND ADMINISTRATION
Melanoma: Confirm the presence of BRAF V600E mutation in tumor specimens prior to initiation of treatment with Tafinlar as a single agent.

Confirm the presence of BRAF V600E or V600K mutation in tumor specimens prior to initiation of treatment with Tafinlar in combination with trametinib.

The recommended dose is 150 mg orally taken twice daily in combination with trametinib until disease recurrence or unacceptable toxicity for up to 1 year.

Unresectable or Metastatic Melanoma: The recommended dose is 150 mg orally taken twice daily, as a single agent or in combination with trametinib, until disease progression or unacceptable toxicity.

NSCLC and ATC: Confirm the presence of BRAF V600E mutation in tumor specimens prior to initiation of treatment with Tafinlar in combination with trametinib.

The recommended dose is 150 mg orally taken twice daily in combination with trametinib until disease recurrence or unacceptable toxicity.

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DABRAFENIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Take Tafinlar at doses approximately 12 hours apart. Take at least 1 hour before or 2 hours after a meal. Do not take a missed dose within 6 hours of the next dose of Tafinlar. Do not open, crush, or break Tafinlar capsules.

Recommended Dose Reductions for Tafinlar for Adverse Reactions:

Dose Reductions	Dose and Schedule
First dose reduction	100 mg orally twice daily
Second dose reduction	75 mg orally twice daily
Third dose reduction	50 mg orally twice daily
Subsequent modification	Permanently discontinue Tafinlar if unable to tolerate 50 mg twice daily

REFERENCES

- Tafinlar [Prescribing Information]. East Hanover, New Jersey: 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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Client Approval: 05/18

P&T Approval: 07/18