

## Pre - PA Allowance

None

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## Prior-Approval Requirements

### Diagnoses

Patient must have **ONE** of the following:

1. Unresectable or metastatic melanoma
  - a. 18 years of age or older
  - b. Patient has **ONE** of the following:
    - i. Used as a single agent with documented BRAF V600E mutation as detected by an FDA-approved test
    - ii. Used in combination with trametinib (Mekinist) with documented BRAF V600E or BRAF V600K mutation as detected by an FDA-approved test
2. Resectable melanoma
  - a. 18 years of age or older
  - b. Used in combination with trametinib (Mekinist) with documented BRAF V600E or BRAF V600K mutation as detected by an FDA-approved test
  - c. Melanoma has lymph node involvement
  - d. Used as adjuvant treatment after complete resection
3. Metastatic non-small cell lung cancer (NSCLC)
  - a. 18 years of age or older
  - b. Used in combination with trametinib (Mekinist) with documented BRAF V600E mutation as detected by an FDA-approved test
4. Locally advanced or metastatic anaplastic thyroid cancer (ATC)
  - a. 18 years of age or older
  - b. Used in combination with trametinib (Mekinist) with documented BRAF V600E mutation
  - c. **NO** satisfactory locoregional treatment options
5. Unresectable or metastatic solid tumors
  - a. 1 year of age or older
  - b. Used in combination with trametinib (Mekinist) with documented BRAF V600E mutation



**TAFINLAR**  
**(dabrafenib)**

- c. Patient has progressed following prior treatment
- d. **NO** satisfactory alternative treatment options

6. Low-grade glioma (LGG)

- a. 1 year of age or older
- b. Used in combination with trametinib (Mekinist) with documented BRAF V600E mutation
- c. Patient requires systemic therapy
- d.

**AND** the following for **ALL** indications:

- a. Females of reproductive potential **only**: patient will be advised to use effective non-hormonal contraception during treatment with Tafinlar and for 2 weeks after the last dose

## Prior - Approval Limits

### Quantity

| Strength | Quantity       |
|----------|----------------|
| 10 mg    | 300 mg per day |
| 50 mg    |                |
| 75 mg    |                |

**Duration** 12 months

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## Prior – Approval *Renewal* Requirements

**No renewal for resectable melanoma diagnosis**

### Diagnoses

Patient must have **ONE** of the following:

1. Unresectable or metastatic melanoma
  - a. 18 years of age or older
  - b. Used as a single agent **OR** used in combination with trametinib (Mekinist)
2. Metastatic non-small cell lung cancer (NSCLC)
  - a. 18 years of age or older
  - b. Used in combination with trametinib (Mekinist)
3. Locally advanced or metastatic anaplastic thyroid cancer (ATC)



**TAFINLAR  
(dabrafenib)**

- a. 18 years of age or older
  - b. Used in combination with trametinib (Mekinist)
4. Unresectable or metastatic solid tumors
- a. 1 year of age or older
  - b. Used in combination with trametinib (Mekinist)
5. Low-grade glioma (LGG)
- a. 1 year of age or older
  - b. Used in combination with trametinib (Mekinist)

**AND ALL** of the following for **ALL** indications:

- a. **NO** disease progression or unacceptable toxicity
- b. Females of reproductive potential **only**: patient will be advised to use effective non-hormonal contraception during treatment with Tafenlar and for 2 weeks after the last dose

**Prior – Approval *Renewal* Limits**

Same as above

**No renewal for resectable melanoma diagnosis**