BlueCross BlueShield Federal Employee Program

TAFINLAR
(dabrafenib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Tafinlar (dabrafenib) is an inhibitor of some mutated forms of BRAF kinases. Some mutations in the BRAF gene, including those that result in BRAF V600E, can result in constitutively activated BRAF kinases that may stimulate tumor cell growth. Tafinlar inhibits cell growth of carious BRAF V600 mutation-positive tumors. Tafinlar and trametinib (Mekinist) inhibit different kinases in the pathways involved in these tumors. Use of these two agents together results in greater growth inhibition of BRAF V600 mutation-positive tumor cell lines (1).

Regulatory Status

FDA-approved indications: Tafinlar is a kinase inhibitor indicated: (1)

1. 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.
2. In combination with trametinib (Mekinist) for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
3. In combination with trametinib (Mekinist) for 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.
4. In combination with trametinib (Mekinist) for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test.
5. In combination with trametinib (Mekinist) for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.
6. In combination with trametinib (Mekinist) for the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.
7. In combination with trametinib (Mekinist) for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

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Limitations of Use: (1)

Tafinlar is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Tafinlar is not indicated for the treatment of wild-type BRAF solid tumors.

Prior to initiation of therapy, the presence of BRAF V600E or V600K mutation in tumor specimens must be confirmed (1).

Hemorrhages, including major hemorrhages defined as symptomatic bleeding in a critical area or organ can occur in patients receiving Tafinlar. Permanently discontinue Tafinlar for all Grade 4 hemorrhagic events and for any Grade 3 hemorrhagic events that do not improve. Withhold Tafinlar for Grade 3 hemorrhagic events; if improved, resume at the next lower dose level (1).

Venous thromboembolism, such as deep vein thrombosis and pulmonary embolism, can occur in patients receiving Tafinlar (1).

Tafinlar has a risk of developing cardiomyopathy. Assess left ventricular ejection fraction (LVEF) by echocardiogram or multigated acquisition (MUGA) scan before initiation of Tafinlar, one month after initiation of Tafinlar, and then every 2 to 3 during treatment (1).

There is a risk of uveitis in patients treated with Tafinlar. Patients should be monitored for visual signs and symptoms of uveitis (1).

There is a potential risk of skin toxicity while taking Tafinlar. Patients should be monitored for new or worsening serious skin reactions (1).

There is a potential risk of hemolytic anemia in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Patients with G6PD deficiency should be monitored for signs of hemolytic anemia while taking Tafinlar (1).

Tafinlar can cause embryo-fetal toxicity and impaired fertility. Advise female patients of reproductive potential to use effective non-hormonal contraception during treatment with Tafinlar

and for 2 weeks after the last dose (1).

The safety and effectiveness of Tafinlar in combination with trametinib (Mekinist) have not been established in pediatric patients less than 1 year old with unresectable or metastatic solid tumors and with LGG. The safety and effectiveness of Tafinlar for all other indications in pediatric patients have not been established (1).

Summary

Tafinlar (dabrafenib) is indicated for the treatment of unresectable or metastatic melanoma; resectable melanoma; metastatic non-small cell lung cancer (NSCLC); locally advanced or metastatic anaplastic thyroid cancer (ATC); unresectable or metastatic solid tumors; and low-grade glioma (LGG). Tafinlar has several warnings including hemorrhage, cardiomyopathy, uveitis, serious skin toxicities, hemolytic anemia, and embryo-fetal toxicity (1-3).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Tafinlar while maintaining optimal therapeutic outcomes.

References

1. Tafinlar [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2024.
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3. NCCN Clinical Practice Guidelines in Oncology® Cutaneous Melanoma (Version 2.2024). National Comprehensive Cancer Network, Inc. April 2024. Accessed on July 11, 2024.
4. NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 7.2024). National Comprehensive Cancer Network, Inc. June 2024. Accessed on July 11, 2024.