BlueCross BlueShield Federal Employee Program

LENVIMA
(lenvatinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Lenvima (lenvatinib) is used to treat patients with progressive, differentiated thyroid cancer (DTC) whose disease progressed despite receiving radioactive iodine therapy (radioactive iodine refractory disease). DTC is a cancerous growth of the thyroid gland which is located in the neck and helps regulate the body's metabolism. Lenvima is also used to treat patients with renal cell carcinoma, unresectable hepatocellular carcinoma, or endometrial carcinoma. Lenvima is a receptor tyrosine kinase (RTK) inhibitor which works by blocking certain proteins from helping cancer cells grow and divide (1).

Regulatory Status

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

1. Differentiated Thyroid Cancer (DTC): single agent for patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer
2. Renal Cell Cancer (RCC):
    a. In combination with pembrolizumab, for the first-line treatment of adult patients with advanced RCC
    b. In combination with everolimus, for patients with advanced RCC following one prior anti-angiogenic therapy
3. Unresectable Hepatocellular Carcinoma (HCC): as first-line treatment
4. Advanced endometrial carcinoma (EC): in combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or not microsatellite instability-high (MSI-H), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation

<u>Off-Label Use</u>: (2)

1. Unresectable HCC: as subsequent-line therapy in disease progression if Child-Pugh Class A

Lenvima may cause serious side effects, including cardiac failure, blood clot formation (arterial thromboembolic events), liver damage (hepatotoxicity), kidney damage (renal failure and impairment), an opening in the wall of the stomach or intestines (gastrointestinal perforation) or an

abnormal connection between two parts of the stomach or intestines (fistula formation), changes in the heart's electrical activity (QT interval prolongation), low levels of calcium in the blood (hypocalcemia), the simultaneous occurrence of headache, confusion, seizures and visual changes (reversible posterior leukoencephalopathy syndrome), serious bleeding (hemorrhage), risks to an unborn child if a patient becomes pregnant during treatment, and impairing suppression of the production of thyroid-stimulating hormone (1).

Summary

Differentiated thyroid cancer (DTC) is the most common type of thyroid cancer which is a cancerous growth of the thyroid gland which is located in the neck and helps regulate the body's metabolism. Lenvima is also used to treat patients with renal cell carcinoma, unresectable hepatocellular carcinoma, or endometrial carcinoma. Lenvima is a kinase inhibitor, which works by blocking certain proteins from helping cancer cells grow and divide. Lenvima may cause serious side effects, including cardiac failure, blood clot formation, liver damage, and kidney damage. The safety and effectiveness of Lenvima in pediatric patients have not been established (1).

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

References

1. Lenvima [package insert]. Woodcliff Lake, New Jersey: Eisai Inc.; November 2025.
2. NCCN Drugs & Biologics Compendium® Lenvatinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025.