BlueCross BlueShield Federal Employee Program

INLYTA
(axitinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Inlyta (axitinib) is used to treat advanced kidney cancer when one prior treatment has failed or as first-line treatment in combination with Keytruda or Bavencio. It works by blocking certain proteins called kinases that play a role in tumor growth and cancer progression. Inlyta has been shown to inhibit receptor tyrosine kinases including vascular endothelial growth factor receptors (VEGFR)-1, VEGFR-2, and VEGFR-3. These receptors are implicated in tumor blood vessel generation, tumor growth, and cancer progression (1).

Regulatory Status

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

1. in combination with avelumab, for the first-line treatment of patients with advanced renal cell carcinoma (RCC).
2. in combination with pembrolizumab, for the first-line treatment of patients with advanced RCC.
3. as a single agent, for the treatment of advanced renal cell carcinoma.

Inlyta should be used with caution in patients at increased risk for thrombotic events, hemorrhagic events, gastrointestinal perforation, and fistula. Patients with untreated brain metastasis or active gastrointestinal bleeding should not use Inlyta. Inlyta should be stopped at least 24 hours prior to scheduled surgery. Patients should be monitored for hypothyroidism, proteinuria, liver enzyme elevations, and cardiac failure. Permanently discontinue Inlyta if reversible posterior leukoencephalopathy syndrome occurs (1).

The safety and efficacy of Inlyta in pediatric patients have not been studied (1).

Summary

Inlyta is a kinase inhibitor indicated for the treatment of advanced renal cell carcinoma after failure of one prior systemic therapy or as first-line treatment in combination with Keytruda or Bavencio. Inlyta should not be used in patients with evidence of untreated brain metastasis, recent active gastrointestinal bleeding, or reversible posterior leukoencephalopathy syndrome (RPLS). Inlyta should be used in caution in patients at risk for gastrointestinal perforation or fistula, arterial and venous thrombotic events, and hepatic impairment. The safety and efficacy of Inlyta in pediatric

patients have not been studied (1).

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

References

1. Inlyta [package insert]. New York, NY: Pfizer Labs; July 2024.
1. NCCN Drugs & Biologics Compendium® Axitinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.