BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.034

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	April 26, 2013
Subject:	Inlyta	**Page:**	1 of 4

Last Review Date: March 7, 2025

Inlyta

Description

Inlyta (axitinib)

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).

Related policies
Cabometyx, Fotivda, Lenvima, Nexavar, Sutent, Votrient

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Inlyta may be considered **medically necessary** if the conditions indicated below are met.

Inlyta may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Advanced renal cell carcinoma
    a. Obtain ALT, AST and bilirubin prior to initiation of therapy and monitor during therapy

AND ONE of the following:
a. Failure of one prior first-line systemic therapy
b. First-line treatment in combination with Keytruda (pembrolizumab)
c. First-line treatment in combination with Bavencio (avelumab)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Advanced renal cell carcinoma

AND NONE of the following:

a. Gastrointestinal perforation or fistula
b. Signs and symptoms of reversible posterior leukoencephalopathy syndrome (RPLS)
c. Severe hepatic impairment

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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.

2. NCCN Drugs & Biologics Compendium® Axitinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.

Policy History

Date	Action
June 2013	Addition to PA
September 2014	Annual editorial and reference update Removal of monitoring of proteinuria
June 2016	Annual editorial review and reference update Removal of first line examples Policy code changed from 5.04.34 to 5.21.34
June 2017	Annual editorial review
June 2018	Annual editorial review
April 2019	Addition of indication: RCC as first-line treatment in combination with Keytruda
May 2019	Addition of indication: RCC as first-line treatment in combination with Bavencio
June 2019	Annual review
June 2020	Annual review and reference update
June 2021	Annual review and reference update
June 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.21.034
March 2024	Annual review and reference update
March 2025	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.