



# 5.21.34

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2022
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	April 26, 2013
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**Last Review Date:** June 16, 2022

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## 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 indication: Inlyta is a kinase inhibitor indicated for: (1)

1. The treatment of advanced renal cell carcinoma after failure of one prior systemic therapy.
2. The first-line treatment of advanced renal cell carcinoma in combination with pembrolizumab.
3. The first-line treatment of advanced renal cell carcinoma in combination with avelumab.

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).

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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** in patients that are 18 years of age and older with advanced renal cell carcinoma and if the conditions indicated below are met.

Inlyta may be considered **investigational** in patients that are less than 18 years of age and 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:

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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; June 2020.

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2. NCCN Drugs & Biologics Compendium<sup>®</sup> Axitinib 2022. National Comprehensive Cancer Network, Inc. Accessed on April 18, 2022.

## 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

## Keywords

**This policy was approved by the FEP<sup>®</sup> Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.**