

## Clinical Policy: Axitinib (Inlyta)

Reference Number: ERX.SPA.46

Effective Date: 07.01.16

Last Review Date: 02.21

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

### Description

Axitinib (Inlyta®) is a kinase inhibitor.

### FDA Approved Indication(s)

Inlyta is indicated:

- In combination with avelumab, for the first-line treatment of patients with advanced renal cell carcinoma (RCC).
- In combination with pembrolizumab, for the first-line treatment of patients with advanced RCC.
- As a single agent, for the treatment of advanced RCC after failure of one prior systemic therapy.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Inlyta is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Renal Cell Carcinoma (must meet all):

1. Diagnosis of relapsed, metastatic, or stage IV RCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For Inlyta request, medical justification supports inability to use axitinib, if available (e.g., contraindications to excipients);
5. Prescribed in one of the following ways (a or b):
  - a. As single-agent therapy;
  - b. For clear cell histology, in combination with Keytruda® or Bavencio®;\*
6. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 20 mg (4 tablets) per day;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*Prior authorization may be required*

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

##### Approval duration:

**Medicaid** – 6 months

**Commercial** – Length of Benefit

##### B. Thyroid Carcinoma (off-label) (must meet all):

1. Diagnosis of differentiated thyroid carcinoma (DTC; i.e., follicular, Hurthle cell or papillary thyroid carcinoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;

4. For Inlyta request, medical justification supports inability to use axitinib, if available (e.g., contraindications to excipients);
5. Disease is unresectable locoregional recurrent, persistent, or metastatic;
6. Failure of Lenvima® or Nexavar®, unless both are contraindicated or clinically adverse effects are experienced;  
*\*Prior authorization may be required*
7. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).\*  
*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**

**Medicaid – 6 months**

**Commercial – Length of Benefit**

**C. Other diagnoses/indications**

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. All Indications in Section I (must meet all):**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Inlyta for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Inlyta request, medical justification supports inability to use axitinib, if available (e.g., contraindications to excipients);
4. If request is for a dose increase, request meets one of the following (a or b):\*
  - a. New dose does not exceed 20 mg (4 tablets) per day;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**

**Medicaid – 12 months**

**Commercial – Length of Benefit**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 6 months (whichever is less);** or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

DTC: differentiated thyroid carcinoma

FDA: Food and Drug Association

NCCN: National Comprehensive Cancer Network

RCC: renal cell carcinoma

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria.*

*The drugs listed here may not be a formulary agent and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit Maximum Dose
<i>DTC</i>		
Lenvima (lenvatinib)	24 mg PO QD	24 mg/day
Nexavar (sorafenib)	400 mg PO QD	400 mg/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

**Appendix C: Contraindications/Boxed Warnings**

None reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
RCC	Single-agent therapy <ul style="list-style-type: none"> <li>5 mg PO BID</li> </ul> Combination therapy: <ul style="list-style-type: none"> <li>5 mg PO BID with avelumab 800 mg every 2 weeks.</li> <li>5 mg PO BID with pembrolizumab 200 mg every 3 weeks or 400 mg every 6 weeks.</li> </ul>	20 mg/day

**VI. Product Availability**

Tablets: 1 mg, 5 mg

**VII. References**

1. Inlyta Prescribing Information. New York, NY: Pfizer Labs, Inc.; June 2020. Available at <http://labeling.pfizer.com/ShowLabeling.aspx?id=759>. Accessed November 14, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed November 14, 2020.
3. National Comprehensive Cancer Network Guidelines. Kidney Cancer Version 1.2021. Available at: nccn.org. Accessed November 14, 2020.
4. National Comprehensive Cancer Network Guidelines. Thyroid Carcinoma Version 2.2020. Available at: nccn.org. Accessed November 14, 2020.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: <http://www.clinicalpharmacology-ip.com/>.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Renal cancer is reorganized around FDA labeled and NCCN recommended uses; dosing removed. Approval duration changed to 6 months for initial and 12 months for continued for indications specifically addressed in the policy.	04.17	05.17
1Q18 annual review: Age, specialist and dosing added. Renal cell carcinoma: definition of "advanced" removed given the additional requirement of a prior systemic therapy. References updated. Approval durations modified to length of benefit.	11.22.17	02.18
1Q 2019 annual review: thyroid carcinoma - DTC is added to diagnosis for clarity, metastatic/iodine refractory is removed and a drug trial is added per NCCN; references reviewed and updated.	11.13.18	02.19
1Q 2020 annual review: for RCC with clear cell histology added additional approval pathway for concurrent use with Keytruda or Bavencio consistent with NCCN Compendium; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	10.24.19	02.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: oral oncology generic redirection language added; for RCC, relapsed, stage IV, or metastatic disease added, clear cell histology restriction limited to combination therapy with Keytruda and Bacencio, single-agent first-line therapy added per NCCN; for thyroid carcinoma, unresectable locoregional recurrent, persistent or metastatic disease added per NCCN; references reviewed and updated.	11.14.20	02.21

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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