

## Clinical Policy: Axitinib (Inlyta)

Reference Number: MDN.CP.PHAR.100

Effective Date: 12.1.24

Last Review Date: 11.6.24

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Axitinib (Inlyta<sup>®</sup>) 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 (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> 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  $\geq$  18 years;
4. Prescribed in one of the following ways (a or b):
  - a. As single-agent therapy;
  - b. For clear cell histology, in combination with Keytruda<sup>®</sup> or Bavencio<sup>®</sup>;  
*\*Prior authorization may be required*
5. Request meets one of the following (a or b):
  - c. Dose does not exceed 20 mg per day;
  - d. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

##### Approval duration:

Medicaid - 6 months

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

1. Diagnosis of differentiated thyroid carcinoma (DTC; i.e., follicular, oncocytic (formerly known as Hurthle cell) or papillary thyroid carcinoma);
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Disease is both of the following (a and b):
  - a. Unresectable locoregional recurrent, persistent, or metastatic;
  - b. Progressive and/or symptomatic;
5. Disease is not amenable to radioactive iodine therapy;
6. Failure of Nexavar<sup>®</sup>, unless both are contraindicated or clinically adverse effects are experienced;  
*\*Prior authorization may be required*
7. Clinical trials or other systemic therapies are not available or appropriate (*see Appendix B*);\*  
*\*Prior authorization may be required*
8. 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).

**Approval duration:**

**Medicaid - 6 months**

**C. Soft Tissue Sarcoma (off-label) (must meet all):**

1. Diagnosis of alveolar soft part sarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Prescribed in combination with Keytruda<sup>®</sup>;\*  
*\*Prior authorization may be required*
5. 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**

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

## II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, 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. 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**

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
    - a. For drugs on the (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
    - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
  2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business CP.PMN.53 for Medicaid.
1. .

## 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 policies – CP.PMN.53 for Medicaid 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 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>Examples of RCC first and second-line therapies for relapse or stage IV disease per NCCN</i>		
<ul style="list-style-type: none"> <li>• Votrient<sup>®</sup> (pazopanib)</li> <li>• Sutent<sup>®</sup> (sunitinib)</li> <li>• Opdivo<sup>®</sup> (nivolumab)</li> <li>• Avastin<sup>®</sup> (bevacizumab) ± Tarceva (erlotinib) or Afinitor<sup>®</sup>/Afinitor<sup>®</sup> Disperz (everolimus))</li> <li>• Cabometyx<sup>®</sup> (cabozantinib)</li> <li>• Torisel<sup>®</sup> (temsirolimus)</li> <li>• Inlyta<sup>®</sup> (axitinib)</li> <li>• Afinitor/Afinitor Disperz (everolimus) ± Lenvima (lenvatinib)</li> <li>• Tarceva<sup>®</sup> (erlotinib)</li> </ul>	Varies	Varies
<b>DTC</b>		
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.; September 2022. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/202324Orig1s014CorrectedLbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/202324Orig1s014CorrectedLbl.pdf). Accessed October 03,2023.

2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed October 17, 2023.
3. National Comprehensive Cancer Network Guidelines. Kidney Cancer Version 1.2024. Available at: nccn.org. Accessed October 17, 2023.
4. National Comprehensive Cancer Network Guidelines. Thyroid Carcinoma Version 4.2023. Available at: nccn.org. Accessed October 17, 2023.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc. Updated periodically. Accessed October 17, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created, adapted IL.PHAR.100 Axitinib (Inlyta) policy for migration to HFS PDL	11.6.24	

**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace members,** when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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