Clinical Policy:Axitinib (Inlyta)

Reference Number: CP.PHAR.100
Effective Date: 05/12
Last Review Date: 04/17

Coding Implications
Revision Log

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for axitinib (Inlyta®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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 advanced renal cell carcinoma (i.e., relapsed or surgically unresectable stage IV disease);
2. Meets a or b:
   a. FDA approved use:
      i. Subsequent therapy (has failed at least one prior systemic therapy);
   b. Off-label NCCN recommended use:
      i. First-line therapy for clear cell or non-clear cell histology.

Approval duration: 6 months

B. Thyroid Carcinoma – Off-label Use (must meet all):

1. Diagnosis of one of the following types of thyroid carcinoma:
   a. Follicular carcinoma;
   b. Hürthle cell carcinoma;
   c. Papillary carcinoma;
2. The cancer is positive for one or more of the following characteristics:
   a. Progressive disease;
   b. Symptomatic, iodine-refractory and either i or ii:
      i. Unresectable, recurrent or persistent locoregional disease;
      ii. Distant metastatic disease;
3. Other systemic therapies FDA approved for the above-referenced types of thyroid carcinoma are ineffective, contraindicated or unavailable.

Approval duration: 6 months

C. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Renal Cell and Thyroid Carcinomas (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has met all initial approval criteria;
2. Documentation of positive response to therapy (e.g.: no disease progression; not experiencing unacceptable toxicity).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy;
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:
Axitinib is an oral agent that works by inhibiting receptor tyrosine kinases, including vascular endothelial growth factor receptors (VEGFR)-1, VEGFR-2, and VEGFR-3. These receptors are implicated in pathologic angiogenesis, tumor growth, and cancer progression.

FDA Approved Indications:
Inlyta is a kinase inhibitor/oral tablet formulation indicated for:
- Treatment of advanced renal cell carcinoma after failure of one prior systemic therapy

Appendices

Appendix A: Abbreviation Key
VEGFR: vascular endothelial growth factor receptor

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Converted to Centene policy template	06/13	06/13
Updated background and safety sections. Removed duplicate questioning within algorithm regarding prior use of Inlyta.	06/14	06/14

Reviews, Revisions, and Approvals	Date	Approval Date
Updated RCC statistics in background section. Added contraindications and monitoring requirements in algorithm as outlined in new appendices. Updated references	04/15	05/15
Policy converted to new template. Requests for documentation are removed for renal cell carcinoma. Defined advanced renal cell cancer per NCCN compendium. Allow first-line use (based on NCCN recommendation) when other FDA approved systemic therapies for renal cell cancer are contraindicated or unavailable. Removed requirement for baseline monitoring and oncologist prescriber. Added approval criteria for thyroid carcinoma per NCCN 2A recommendation.	04/16	05/16
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. Safety criteria is removed as there are no contraindications or black box warnings.	03/17	04/17

References

1. Inlyta prescribing information. New York, NY: Pfizer Labs, Inc.; August 2014. Available at http://labeling.pfizer.com/ShowLabeling.aspx?id=759. Accessed March 23, 2017.
2. Axitinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed March 29, 2017.
3. Kidney cancer (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed March 29, 2017.

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.