

SPECIALTY GUIDELINE MANAGEMENT

INLYTA (axitinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

Inlyta is indicated for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy

B. Compendial Uses

1. Relapsed or surgically unresectable renal cell carcinoma
2. Papillary, Hürthle cell, or follicular thyroid carcinoma:
 - a. Unresectable recurrent or persistent locoregional disease
 - b. Distant metastatic disease

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Renal Cell Carcinoma**

Authorization of 12 months may be granted to members prescribed Inlyta for the treatment of relapsed or unresectable RCC.

B. **Papillary, Hurthe cell, or Follicular Thyroid Carcinoma**

Authorization of 12 months may be granted to members prescribed Inlyta for the treatment of unresectable or metastatic papillary, Hurthle cell, or follicular thyroid carcinoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Inlyta [package insert]. New York, NY: Pfizer Inc., August 2014.
2. The NCCN Drugs & Biologics Compendium™ © 2015 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed June 28, 2016.
https://www.nccn.org/professionals/drug_compendium/content/contents.asp.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer. Version 3.2016. Accessed July 30, 2016. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. Version 1.2016. Accessed August 01, 2016.
https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf/