

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 stage IV renal cell carcinoma
2. Papillary, Hürthle cell, or follicular thyroid carcinoma

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 for treatment of relapsed, metastatic, or unresectable RCC.

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

Authorization of 12 months may be granted for treatment of 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® © 2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed July 24, 2017.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer. Version 2.2017. Accessed July 24, 2017. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Thyroid Carcinoma. Version 2.2017. Accessed July 24, 2017. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf.