Reference number
2079-A

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
   1. First-Line Advanced Renal Cell Carcinoma
      a. Inlyta in combination with avelumab is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC).
      b. Inlyta in combination with pembrolizumab is indicated for the first-line treatment of patients with advanced renal cell carcinoma.
   2. Second-Line Advanced Renal Cell Carcinoma
      Inlyta as a single agent 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, Oncocytic (Hürthle cell) or Follicular thyroid carcinoma
   3. Soft tissue sarcomas: alveolar soft part sarcoma (ASPS)

All other indications are considered experimental/investigational and not medically necessary.

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with an oncologist.

III. CRITERIA FOR INITIAL APPROVAL

A. Renal Cell Carcinoma
Authorization of 12 months may be granted for treatment of advanced, relapsed, or stage IV renal cell carcinoma when any of the following criteria is met:
1. Inlyta will be used as a single agent
2. Inlyta will be used in combination with pembrolizumab
3. Inlyta will be used as first-line treatment in combination with avelumab

B. Papillary, Oncocytic (Hürthle cell), or Follicular Thyroid Carcinoma
Authorization of 12 months may be granted for treatment of progressive and/or symptomatic papillary, Oncocytic (Hürthle cell), or follicular thyroid carcinoma that is not amenable to radioactive iodine (RAI) therapy.

C. Soft Tissue Sarcomas
Authorization of 12 months may be granted for treatment of alveolar soft part sarcoma (ASPS) subtype of soft tissue sarcoma when used in combination with pembrolizumab.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Inlyta [package insert]. New York, NY: Pfizer Inc., September 2022.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 7, 2024.