Reference number(s)
2079-A

Specialty Guideline Management
Inlyta

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Inlyta	axitinib

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.

FDA-approved Indications[1]

First-Line Advanced Renal Cell Carcinoma

Inlyta in combination with avelumab is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC).
Inlyta in combination with pembrolizumab is indicated for the first-line treatment of patients with advanced RCC.

Second-Line Advanced Renal Cell Carcinoma

Inlyta as a single agent is indicated for the treatment of advanced RCC after failure of one prior systemic therapy.

Compendial Uses[2]

- Relapsed or stage IV renal cell carcinoma
- Papillary, Oncocytic (Hürthle cell), or Follicular thyroid carcinoma

- Soft tissue sarcomas: alveolar soft part sarcoma (ASPS)
- Thymic carcinoma

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

Prescriber Specialties

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

Coverage Criteria

Renal Cell Carcinoma[1,2]

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:

- Inlyta will be used as a single agent for either of the following:
  - First-line therapy for non-clear cell histology.
  - Subsequent therapy.
- Inlyta will be used in combination with pembrolizumab for either of the following:
  - First-line therapy.
  - Subsequent therapy for clear cell histology.
- Inlyta will be used as first-line treatment in combination with avelumab.

Papillary, Oncocytic (Hürthle cell), or Follicular Thyroid Carcinoma[2]

Authorization of 12 months may be granted for treatment of progressive and/or symptomatic disease that meets either of the following:

- Unresectable, persistent, or metastatic Oncocytic (Hürthle cell) thyroid carcinoma.
- Unrestable, persistent, or metastatic papillary or follicular thyroid carcinoma not amenable to radioactive iodine (RAI) therapy.

Soft Tissue Sarcomas[2]

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.

Thymic Carcinoma[2]

Authorization of 12 months may be granted for treatment of thymic carcinoma when both of the following criteria are met:

- The requested medication will be used as subsequent therapy or in members who cannot tolerate first-line combination regimens.
- The requested medication will be used in combination with avelumab.

Continuation of Therapy

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

References

1. Inlyta [package insert]. New York, NY: Pfizer Inc.; July 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 14, 2025.