| Reference number(s) |
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| 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 (RCC)

First-line treatment of patients with advanced RCC in combination with avelumab
First-line treatment of patients with advanced RCC in combination with pembrolizumab

#### Second-Line Advanced Renal Cell Carcinoma

Treatment of advanced RCC as a single agent after failure of one prior systemic therapy

### Compendial Uses[2]

- Relapsed or stage IV renal cell carcinoma
- Endometrial 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.


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# Prescriber Specialties

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

# Documentation

Submission of the following information is necessary to initiate the prior authorization review: Documentation of laboratory report confirming mismatch repair proficient (pMMR) tumor status, where applicable.

# 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:

- The requested medication will be used as a single agent for either of the following:
  - First-line therapy for non-clear cell histology.
  - Subsequent therapy.
- The requested medication will be used in combination with pembrolizumab (Keytruda) for either of the following:
  - First-line therapy.
  - Subsequent therapy for clear cell histology.
- The requested medication will be used in combination with avelumab (Bavencio) as first-line treatment.

## Endometrial Carcinoma[2]

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

- The tumor is mismatch repair proficient (pMMR).
- The requested medication will be used in combination with avelumab (Bavencio).

## Papillary, Oncocytic /Hürthle Cell, or Follicular Thyroid Carcinoma[2]

Authorization of 12 months may be granted for treatment papillary, oncocytic/Hürthle cell, or follicular thyroid carcinoma as a single agent when both of the following criteria are met:

- The disease is locoregional, unresectable, progressive and/or symptomatic, or metastatic.
- Radioactive iodine (RAI) therapy is not indicated, is contraindicated, or has been unsuccessful.


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### Soft Tissue Sarcomas[2]

Authorization of 12 months may be granted for treatment of alveolar soft part sarcoma (ASPS) in combination with pembrolizumab (Keytruda).

### 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 (Bavencio).

## 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® © 2026 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 6, 2026.


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