

Axitinib (INLYTA) Criteria for Use September 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or [PBM INTRAnet](#) for further information.

Exclusion Criteria¹

If the answer to ANY item below is met, then the patient should NOT receive Axitinib.

- Major surgery in the previous 4 weeks
- Active (unstable) CNS metastasis; stable brain metastases not requiring steroids is allowed
- Uncontrolled hypertension
- Current serious wound that is not healing
- Clinically significant gastrointestinal disorder²
- Uncontrolled active infection
- Pregnancy (i.e. known pregnancy or positive pregnancy test)
- Breastfeeding

¹Caution with use in untreated deep vein thrombosis or pulmonary embolism

²e.g. active GI bleeding, intraluminal metastatic disease with suspected bleeding, inflammatory bowel disease, ulcerative colitis, other GI conditions associated with an increased risk of perforation.

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- Care is provided by a VA/VA purchased care oncology provider
- Eastern Cooperative Oncology Group (ECOG) performance status 0-1
- Goals of care and role of Palliative Care consult have been discussed and documented
- Female patients of child-bearing potential: counseling provided on contraception and risks vs. benefits of treatment
- Males with female partners of child-bearing potential: use effective contraception during therapy and for 1 week after the last dose

Additional Inclusion Criteria^{1,2}

The answer to ONE of the following must be fulfilled in order to meet criteria:

- In combination with pembrolizumab for the first-line treatment of patients with advanced renal cell carcinoma
- As a single agent, for the treatment of advanced renal cell carcinoma after failure of 1 prior systemic therapy

¹Avoid concomitant CYP3A/4 inhibitors (including grapefruit juice). If unavoidable, reduce axitinib dose. Avoid Strong CYP3A/4 Inducers.

²At baseline, assess blood pressure and dipstick urine for protein. Monitor both periodically during therapy.

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