



Prior Authorization Approval Criteria

Xalkori (crizotinib)

Generic name:	crizotinib
Brand name:	Xalkori
Medication class:	Tyrosine kinase inhibitor; antineoplastic
FDA-approved uses:	Locally advanced or metastatic non-small cell lung cancer that is anaplastic lymphoma kinase - positive
Available dosage forms:	250mg and 200mg capsules
Usual dose:	250mg twice daily
Approximate monthly cost: (based on AWP 2011)	\$11,500
Duration of therapy:	Until patient no longer derives clinical benefit

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Advanced or metastatic non-small cell lung cancer (NSCLC) in patients with anaplastic lymphoma receptor tyrosine kinase genetic mutation
- Approval for 3 months at a time

Criteria for continuation of therapy:

- Patient is deriving clinical benefit from treatment
- ALT and total bilirubin levels are being monitored at least monthly

Caution:

- Pneumonitis
- Elevations in ALT and total bilirubin
- QT interval prolongation

Monitoring:

- Monthly ALT and total bilirubin levels

Not approved if:

- Does not meet above criteria

Special considerations:

- ALK gene mutations occur in 1-7% of patient with NSCLC
- ALK mutations are associated with non-smoking patients
- No data available demonstrating improvement in patient outcomes or survival

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/14/11