CRIZOTINIB

Generic	Brand	HICL	GCN	Exception/Other
CRIZOTINIB	XALKORI	37916		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meets **ONE** of the following criteria?
   - Presence of anaplastic lymphoma kinase (ALK-) positive tumors
   - Presence of ROS1-positive tumors

   If yes, **approve for 12 months by HICL with a quantity limit of #2 capsules per day.**
   If no, do not approve.
   DENIAL TEXT: Our guideline for **CRIZOTINIB (Xalkori)** requires a diagnosis metastatic non-small cell lung cancer (NSCLC) with anaplastic lymphoma kinase (ALK-) positive OR ROS1-positive tumors.

RATIONALE

Based on FDA approved indications and dosing.

Lung cancer is the leading cause of cancer death worldwide. About 85% of lung cancers are NSCLC, making it the most common type of lung cancer. However, only 2-7% of patients with NSCLC are ALK-positive. ROS1-positive NSCLC represents another particular molecular subgroup of NSCLC occurring in approximately 1% of NSCLC cases.

NSCLC remains difficult to treat, particularly in the metastatic setting. Approximately 75% of NSCLC patients are diagnosed late with metastatic, or advanced, disease where the five-year survival rate is only 5%.

Information on FDA-approved tests for the detection of ALK rearrangements in NSCLC is available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm

An FDA-approved test for the detection of ROS1 rearrangements in NSCLC is not currently available.

FDA APPROVED INDICATIONS

Xalkori is a kinase inhibitor indicated for the treatment of patients with:
- Metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
- Metastatic NSCLC whose tumors are ROS1-positive.

CONTINUED ON NEXT PAGE

CRIZOTINIB

DOSING

The recommended dose of Xalkori is 250 mg orally, twice daily until disease progression or no longer tolerated by the patient.

If vomiting occurs after taking a dose of Xalkori, take the next dose at the regular time. Dose reduction to 200mg twice daily, 250mg daily, or discontinuation is recommended in the presence of certain toxicities.

REFERENCE

- Xalkori [Prescribing Information]. Pfizer; New York, New York. March 2016.
- Pfizer [online press release]. Available at: http://www.pfizer.com/news/press-release/press-release-detail/pfizer_receives_u_s_fda_breakthrough_therapy_designation_for_xalkori_crizotinib_for_the_treatment_of_patients_with_ros1_positive_non_small_cell_lung_cancer [epub April 21, 2015]. [Accessed March 14, 2016].
- Food and Drug Administration. (2014). FDA approves Zykadia for late-stage lung cancer. http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm395299.htm (Accessed on May 5, 2014)
- Kim DW, Ahn MJ, De Pas TM, et al. Results of a Global Phase II Study with Crizotinib in Advanced ALK-Positive Non-Small-Cell Lung Cancer (NSCLC). Ann Oncol. [Online] October 2012. [Cited: October 4, 2013.] http://annonc.oxfordjournals.org/content/23/suppl_11/xi29.full.pdf+html?sid=881f3ade-513c-44ba-bb50-8cf2b098b4ce
- Shaw AT, Kim DW, Nakagawa K, et al. Crizotinib versus Chemotherapy in Advanced ALK-Positive Lung Cancer. The New England Journal of Medicine 368:2385-94. [Online] June 20, 2013. [Cited: October 4, 2013.] http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214886
- U.S. National Institutes of Health. A Clinical Trial Testing The Efficacy Of Crizotinib Versus Standard Chemotherapy Pemetrexed Plus Cisplatin Or Carboplatin In Patients With ALK Positive Non Squamous Cancer Of The Lung (PROFILE 1014). ClinicalTrials.gov. [Online] September 23, 2013. [Cited: October 7, 2013.] http://clinicaltrials.gov/ct2/show/NCT01154140?term=crizotinib&rank=34
- Phase II Safety and Efficacy Study of Crizotinib in East Asian Patients with ROS1 Positive, ALK Negative Advanced NSCLC. ClinicalTrials.gov. [Online] September 13, 2013. [Cited: October 7, 2013.] http://clinicaltrials.gov/ct2/show/NCT01945021?term=crizotinib+ros1&rank=1
- Tanizaki J, Okamoto I, Okamoto K, et al. MET tyrosine kinase inhibitor crizotinib (PF-02341066) shows differential antitumor effects in non-small cell lung cancer according to MET alterations. J Thorac Oncol. [Online] October 2011. [Cited: October 7, 2013.] http://www.ncbi.nlm.nih.gov/pubmed/21716144

CONTINUED ON NEXT PAGE

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRIZOTINIB

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/16
Created: 09/11
Client Approval: 03/16
P&T Approval: 05/16