Criteria for Nonformulary Use of Erlotinib

VA Pharmacy Benefits Management Strategic Healthcare Group
and Medical Advisory Panel
August 2005

The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data 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 utilize this guidance and interpret it in the clinical context of individual patient situations

Refer to the National PBM Drug Monograph Erlotinib (Tarceva™) at http://vaww.pbm.va.gov/drugmonograph/24t67Erlotinib.pdf or http://www.pbm.va.gov/monograph/24t67Erlotinib.pdf for recommendations on dosing, precautions, and monitoring.

Diagnosis	**#1**
❑ Patient with locally advanced or metastatic non-small cell lung cancer after progression on at least one prior chemotherapy treatment[1] ❑ An option for first-line therapy in patients with bronchioloalveolar carcinoma (BAC) after review on a case by case basis There is not adequate clinical data on use as first-line therapy, other than in patients with BAC, therefore it cannot be recommended at this time.	❑ Yes ❑ No *If Yes, go to #2.* *If No, patient is not eligible for erlotinib* Note: First-line use in combination with chemotherapy did not show a survival advantage
Exclusion Criteria[5]	**#2**
Patient with one of the following conditions: ❑ ECOG Performance Status 4 http://www.ecog.org/general/perf_stat.html ❑ No prior chemotherapy for advanced disease[1](except BAC) ❑ Known central nervous system metastases who are symptomatic or not on a stable dose of corticosteroids for at least 4 weeks prior to start of therapy[2] ❑ Significant history of cardiac disease: uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous year, ventricular dysrhythmia requiring medication ❑ Women of child-bearing potential not using adequate contraception ❑ Women actively breastfeeding. ❑ Clinically significant ophthalmologic or gastrointestinal abnormalities affecting the epithelium: severe dry eye syndrome, keratoconjunctivitis sicca, Sjogren's syndrome, severe exposure keratopathy, uncontrolled Crohn's disease or ulcerative colitis	❑ Yes ❑ No *If No to all conditions, patient is eligible for erlotinib.*
Discontinuation	**#3**
☐ Unacceptable Toxicity ☐ Suspicion of Interstitial Lung Disease- new or progressive dyspnea, cough, and fever ☐ Progressive Disease- at least a 20% increase in the sum of the largest diameter of measurable lesions from baseline or the appearance of new lesions* *There is no evidence of benefit of treating once the disease begins to progress	
Monitoring	**#4**
☐ Routinely monitor AST/ALT and bilirubin[3] ☐ Pulmonary symptoms such as dyspnea, cough and fever ☐ Chest film or CT scan after 1 month, then every 2 months ☐ Potential drug interactions with CYP3A4 inhibitors, inducers and warfarin (or other Coumadin-derived anticoagulants) ☐ Severity of diarrhea[4] (May require loperamide) ☐ Complaints of eye irritation ☐ Dermatologic reactions[4]	

[1] In clinical trials, patients had to receive at least one combination chemotherapy regimen prior to inclusion, except for patients ≥70 years of age who could have received 1 or 2 single agent regimens in keeping with current standards.
[2] Patients with CNS metastases who are asymptomatic or on a stable corticosteroid dose for at least 4 weeks are eligible to receive erlotinib.
[3] LFT increases ≥grade 2 may require dose reduction or interruption in therapy. (ALT >2.5 X ULN)
[4] May require dose reduction or interruption of therapy if severe
[5] Crushing of tablets may be necessary in patients unable to swallow. Turn off tube feeding for 2 hours before administration and for 1 hour after administration as food will increase absorption.

Approved by Physician: Date/Time