
Prior Authorization DRUG Guidelines

TARCEVA™ (Erlotinib)

Effective Date: 7/28/05

Date Developed: 7/13/05 by C. Wilhelmy MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Tarceva is an Antineoplastic Agent, Tyrosine Kinase Inhibitor and Epidermal Growth Factor Receptor (EGFR) Inhibitor/ The mechanism of erlotinib's antitumor action is not fully characterized/ The drug is known to inhibit overall epidermal growth factor receptor (HER1/EGFR)- tyrosine kinase/ Active competitive inhibition of adenosine triphosphate inhibits downstream signal transduction of ligand dependent HER1/EGFR activation/ It is used for salvage therapy of advanced or metastatic nonsmall-cell lung cancer/ Its unlabeled use is for salvage therapy of advanced or metastatic breast, colorectal, and head and neck tumors/

Pre-Authorization Criteria:

FDA Approved Indications

- Maintenance treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has not progressed after four cycles of platinum-based first-line chemotherapy/
- Treatment of locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen/
- First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine/

VCHCP requires that Tarceva be prescribed by an oncologist/

MONITORING PARAMETERS — Periodic liver function tests (asymptomatic increases in liver enzymes have occurred)/

DOSING: ADULTS — Locally advanced or metastatic nonsmall cell lung cancer: Oral: 150 mg/day until disease progression or unacceptable toxicity occurs; dose reduction (if required) should be done in increments of 50 mg/

Dosage adjustment for toxicity: Patients experiencing poorly-tolerated diarrhea or a severe skin reaction may benefit from a brief therapy interruption/ Patients experiencing acute onset (or worsening) of pulmonary symptoms should have therapy interrupted and be evaluated for drug-induced interstitial lung disease/

DOSING: ELDERLY — See adult dosing/

DOSING: HEPATIC IMPAIRMENT — Dose reduction or interruption should be considered if liver function changes are severe/

DOSAGE FORMS — Tablet: 25 mg, 100 mg, 150 mg

ADMINISTRATION — The manufacturer recommends administration on an empty stomach (at least 1 hour before or 2 hours after the ingestion of food) even though this reduces drug absorption by approximately 40%/ Administration after a meal results in nearly 100% absorption/

CONTRAINDICATIONS — Hypersensitivity to erlotinib or any component of the formulation; pregnancy/

WARNINGS / PRECAUTIONS — Rare, sometimes fatal, pulmonary toxicity (interstitial pneumonia, interstitial lung disease, obliterative bronchiolitis, pulmonary fibrosis) has occurred; an interruption of therapy should occur with unexplained pulmonary symptoms (dyspnea, cough, and fever); use caution in hepatic or severe renal impairment/ Safety and efficacy in pediatric patients have not been established/

ETHANOL / NUTRITION / HERB INTERACTIONS

Herb/Nutraceutical: Avoid St John's wort (may increase metabolism and decrease erlotinib concentrations)/

PREGNANCY RISK FACTOR — D

PREGNANCY IMPLICATIONS — Animal studies have demonstrated fetal harm and abortion/ There are no well-controlled studies in pregnant women/ Women of childbearing potential should be advised to avoid pregnancy; adequate contraception is recommended during treatment and for 2 weeks after treatment has been completed/

LACTATION — Excretion in breast milk unknown/not recommended/

TOXICOLOGY / OVERDOSE COMPREHENSIVE — Specific overdose-related toxicities include diarrhea, rash, and liver transaminase elevation/ Overdose management should include withdrawal of erlotinib, and symptom-based and supportive treatment/

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