



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: erlotinib

Brand Name: Tarceva

Medication Class: Human Epidermal Growth Factor Receptor Type1/ Epidermal Growth Factor Receptor (HER1/EGFR) tyrosine kinase inhibitor.

FDA Approved Uses:

- Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) after failure of at least one prior chemotherapy regimen.
Notes: Erlotinib appears to exert modest activity against several cancer types, including NSCLC. Outside of clinical trials, its use should be limited to those indications for which it has been demonstrated to improve survival.
- Locally advanced, unresectable or metastatic Pancreatic Cancer.
Notes: is indicated as first line treatment in combination with gemcitabine.

Usual Dose: Must take one hour before or two hours after the ingestion of food.
NSCLC- 150 mg orally once daily
Pancreatic Cancer- 100 mg orally once daily

Duration of Therapy: Until disease progression or unacceptable toxicity occurs.
Notes: There is not evidence that treatment beyond progression is beneficial.

Criteria for Use for NSCLC: *(bullet points below are all inclusive unless otherwise noted)*
(approved for 3 month period only)

- Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC).
- Failure to at least one prior chemotherapy regimen.
Notes: Results from two multicenter, placebo-controlled, randomized, Phase III trials conducted in first line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of Tarceva with platinum-based chemotherapy and its use are not recommended in this setting.

Criteria for Use for Pancreatic Cancer:

- Clinically documented locally advanced, unresectable or metastatic pancreatic cancer.
- Must be used in combination with gemcitabine.

Contraindications:

- None stated

Not Approved if:

- The patient does not meet the above stated criteria.

P&T Approval: _____ Date: _____