

Specialty Pharmacy Program

Tarceva® (erlotinib)

DESCRIPTION

Tarceva is an oral selective epidermal growth factor receptor-tyrosine kinase inhibitor. Tarceva is indicated for the treatment of non-small cell lung cancer and pancreatic cancer.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

Tarceva may be approved based on the following criteria:

- I. Member has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC)
 - A. Patient has a known epidermal growth factor receptor (EGFR) mutation or EGFR gene amplification OR
 - B. Tarceva is prescribed for maintenance treatment in patients whose disease has not progressed after four cycles of platinum-based chemotherapy OR
 - C. Tarceva is prescribed for treatment of NSCLC after failure of at least one prior chemotherapy regimen.
- II. Member has a diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer
 - A. First-line treatment in combination with gemcitabine

Off-Label Indication(s)

Requests for off-label use of Tarceva will be reviewed and approved when sufficiently supported by evidence from major compendia, published peer-reviewed medical literature, nationally accepted practice guidelines, or expert consensus statements. The major compendia that are recognized include AHFS® Drug Information, Thomson Micromedex®, National Comprehensive Cancer Network Drugs and Biologics Compendium™, and Clinical Pharmacology.