

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

FDA-Approved Indication(s)

1. Treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen.
2. Treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, as 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.