

Generic Name: Erlotinib

Preferred: N/A

Therapeutic Class or Brand Name: Tarceva

Non-preferred: N/A

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/9/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:
 - A. Locally advanced or metastatic non-small cell lung cancer (NSCLC) AND one of criteria 1, 2, or 3 below are met:
 1. Documentation that tumor has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.
 2. Documentation that disease has not progressed after four cycles of platinum-based first-line chemotherapy (i.e. cisplatin, carboplatin).
 3. Documentation of failure of at least one prior chemotherapy regimen prescribed for NSCLC.
 - B. Locally advanced, unresectable, or metastatic pancreatic cancer AND criterion 1 is met:
 1. Must be used in combination with gemcitabine.
- II. Minimum age requirement: 18 years old.
- III. Treatment must be prescribed by or in consultation with an oncologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Coadministration of Tarceva® with platinum-based chemotherapy (i.e. cisplatin, carboplatin).

OTHER CRITERIA

- Use of Tarceva® with strong CYP3A4 inhibitors or inducers, cigarette smoking, or moderate CYP1A2 inducers should be avoided. Exceptions may be made for higher doses of up to 90 tablets per 30 days for CYP3A4 inducers (i.e. carbamazepine, phenytoin, rifampin, rifabutin,

rifapentine, phenobarbital, and St. John's Wort) or up to 60 tablets per 30 days for cigarette smoking or moderate CYP1A2 inducers (i.e. teriflunomide, rifampin, or phenytoin) when concomitant use cannot be avoided.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities of up to 30 tablets per 30 days. See under Other Criteria for possible exceptions for higher doses (up to 90 tablets per 30 days)

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. National Comprehensive Cancer Network (NCCN). Non-Small Cell Lung Cancer. Version 5.2023. Updated November 8, 2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf.
2. National Comprehensive Cancer Network (NCCN). Pancreatic Adenocarcinoma. Version 2.2023. Updated June 19, 2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf
3. Tarceva® [Package insert] South San Francisco, CA: Genentech; October 2016. Available at: http://www.gene.com/download/pdf/tarceva_prescribing.pdf.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.