MEDICATION POLICY

Generic Name: Erlotinib

Therapeutic Class or Brand Name: Tarceva®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 10/8/16

GPI Code: 2153402500

Prior Authorization Criteria (may be considered medically necessary when criteria I through III 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. The prescribing physician is an oncologist.

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.

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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. http://blue.regence.com/trgmedpol/drugs/dru118.pdf.
2. Medi-Span.
3. http://www.gene.com/download/pdf/tarceva_prescribing.pdf.

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Historical Tracking Of Changes Made To Policy	
10/8/2016	1. **Changed** "N/A" **to** "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." **under Other Criteria**. 2. **Changed** "Quantities of up to 30 tablets per 30 days" **to** "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)" **under Quantity/Days Supply Restrictions**.
7/10/2015	1. **Changed** "A. Either locally advanced or metastatic non-small cell lung cancer (NSCLC) and one of criteria 1, 2, or 3 below are met: 1. At least one prior chemotherapy regimen prescribed for NSCLC was not effective (documented disease progression either during or after treatment); 2. Used as a single maintenance chemotherapy after four cycles of platin-based chemotherapy (see Appendix for platin-based therapies); 3. Used as first-line therapy when epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation as detected by an FDA-approved test is present; B. Locally advanced, unresectable or metastatic pancreatic cancer when given in combination with gemcitabine" **to** "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" **under Prior Authorization Criteria**. 2. **Added** "Coadministration of Tarceva® with platinum-based chemotherapy (i.e. cisplatin, carboplatin)" **under Exclusion Criteria**. 3. **Removed** "Examples of Platin-based Therapies for NSCLC" **from Appendix**.
1/24/2014	1. **Adapted policy to new format.** 2. **Added GPI Code**. 3. **Changed** "Used as first-line therapy when an EGFR mutation is present" **to** "Used as first-line therapy when epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation as detected by an FDA-approved test is present" **under Prior Authorization Criteria**. 4. **Added** "Minimum age requirement: 18 years old; The prescribing physician is an oncologist" **to Prior Authorization Criteria**. 5. **Changed Quantity/Days Supply Restrictions from** "Authorized in quantities of up to thirty 150 mg doses per month" **to** "Quantities of up to 30 tablets per 30 days". 6. **Added** "gemcitabine" **to table in Appendix**. 7. **Updated references** to include Medi-Span and package insert.