

### Clinical Pharmacy Program Guidelines for Tarceva

Program	Prior Authorization
Medication	Tarceva <sup>®</sup> (erlotinib)
Issue Date	12/2015
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

#### 1. Background:

Tarceva<sup>®</sup> (erlotinib) is a kinase inhibitor indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.<sup>1</sup> Tarceva is also indicated as first-line treatment for locally advanced, unresectable, or metastatic pancreatic cancer in combination with Gemzar (gemcitabine).<sup>1</sup> In addition, the National Cancer Comprehensive Network (NCCN) also recommends Tarceva for the treatments of chordoma, leptomeningeal metastases, relapsed or stage IV kidney cancer with non-clear cell histology, NSCLC with known sensitizing EGFR mutations, and vulvar cancer.<sup>2</sup>

The safety and efficacy of Tarceva has not been established in patients with NSCLC whose tumors have other EGFR mutations. Tarceva is not recommended for use in combination with platinum-based chemotherapy.<sup>1</sup>

#### 2. Coverage Criteria:

<p><b>A. <u>Pancreatic Cancer</u></b></p> <p><b>1. <u>Initial Authorization</u></b></p> <p>a. <b>Tarceva</b> will be approved based on <b><u>all</u></b> of the following criteria:</p> <p style="padding-left: 40px;">(1) Diagnosis of pancreatic cancer</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 40px;">(2) Disease is <b><u>one</u></b> of the following:</p>
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- (a) Locally advanced
- (b) Unresectable
- (c) Metastatic

**-AND-**

- (3) Used in combination with Gemzar (gemcitabine)

**Authorization will be issued for 12 months.**

**2. Reauthorization**

- a. **Tarceva** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Tarceva therapy

**Authorization will be issued for 12 months.**

**B. Non-Small Cell Lung Cancer (NSCLC)**

**1. Initial Authorization**

- a. **Tarceva** will be approved based on one of the following criteria:

- (1) All of the following:

- (a) Diagnosis of non-small cell lung cancer (NSCLC)

**-AND-**

- (b) Disease is one of the following:

- i. Metastatic
- ii. Recurrent

**-AND-**

- (c) One of the following:

- i. Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
- ii. Tumors are positive for exon 21 (L858R) substitution mutations
- iii. Tumors are positive for a known sensitizing EGFR mutation

(e.g. in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation) [off-label]

**Authorization will be issued for 12 months.**

**2. Reauthorization**

a. **Tarceva** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Tarceva therapy

**Authorization will be issued for 12 months.**

**C. Chordoma (off-label)**

**1. Initial Authorization**

a. **Tarceva** will be approved based on the following criterion:

- (1) Diagnosis of chordoma

**Authorization will be issued for 12 months.**

**2. Reauthorization**

a. **Tarceva** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Tarceva therapy

**Authorization will be issued for 12 months.**

**D. Kidney Cancer (off-label)**

**1. Initial Authorization**

a. **Tarceva** will be approved based on the **all** of the following criteria:

- (1) One of the following:
- (a) Diagnosis of stage IV kidney cancer
  - (b) Disease is relapsed

**-AND-**

(2) Disease is of non-clear cell histology

**Authorization will be issued for 12 months.**

**2. Reauthorization**

a. **Tarceva** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tarceva therapy

**Authorization will be issued for 12 months.**

**E. Central Nervous System (CNS) Cancers (off-label)**

**1. Initial Authorization**

a. **Tarceva** will be approved based on **both** of the following criteria:

(1) Diagnosis of leptomeningeal metastases from NSCLC

**-AND-**

(2) **One** of the following:

(a) Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions

(b) Tumors are positive for exon 21 (L858R) substitution mutations

**Authorization will be issued for 12 months.**

**2. Reauthorization**

a. **Tarceva** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tarceva therapy

**Authorization will be issued for 12 months.**

**F. Vulvar Cancer (off-label)**

**1. Initial Authorization**

**a. Tarceva** will be approved based on the following criterion:

(1) Diagnosis of vulvar cancer

**Authorization will be issued for 12 months.**

**2. Reauthorization**

**a. Tarceva** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tarceva therapy

**Authorization will be issued for 12 months.**

**3. References:**

1. Tarceva [package insert]. South San Francisco, CA: Genentech USA, Inc.; October 2016.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed October 9, 2017.

Program	Prior Authorization - Tarceva (erlotinib)
<b>Change Control</b>	
Date	Change
12/2015	New guideline –combined Gilotrif, Iressa, and Tarceva into a single policy due to similar criteria
6/2016	Updated clinical criteria to align with Employer & Individual’s notification policy, separated Gilotrif, Iressa, and Tarceva into separate policies to align with E&I policies, and updated policy template
12/2016	Simplified coverage criteria for NSCLC and added coverage for NSCLC with a known sensitizing EGFR mutation (per NCCN). Simplified coverage criteria for kidney cancer (per NCCN). Added coverage criteria for vulvar cancer (per NCCN). Updated background, formatting and references.
11/2017	Annual review with no change to clinical coverage criteria. Updated references.