UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tarceva

Program	Prior Authorization
Medication	Tarceva® (erlotinib)
Markets in scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New York, New York EPP, Rhode Island, Pennsylvania- CHIP, New Jersey, South Carolina
Issue Date	12/2015
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

Tarceva® (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 receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.[1] Tarceva is also indicated as first-line treatment for locally advanced, unresectable, or metastatic pancreatic cancer in combination with Gemzar (gemcitabine).[1] In addition, the National Cancer Comprehensive Network (NCCN) also recommends Tarceva for the treatments of chordoma, metastatic brain tumors originating from EGFR sensitizing NSCLC, relapsed or stage IV kidney cancer with non-clear cell histology, NSCLC with known sensitizing EGFR mutations, and vulvar cancer.[2]

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.[1]

2. Coverage Criteria:

A. <u>Pancreatic Cancer</u>

1. <u>Initial Authorization</u>

a. **Tarceva** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of pancreatic cancer

-AND-

(2) Disease is **<u>one</u>** of the following:

(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)

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

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

1. Initial Authorization

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

(1) **Both** of the following:

(a) Diagnosis of kidney cancer
(b) Disease is stage IV or 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

1. Initial Authorization

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

(1) Diagnosis of metastatic brain cancer 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
(c) Tumors are positive for a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation)

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

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.

G. NCCN Recommended Regimens

1. Initial Authorization

a. **Tarceva** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Tarceva therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. 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. Accessed October 5, 2020.

Program	Prior Authorization - Tarceva (erlotinib)
Change Control	
Date	Change
12/2015	New guideline –combined Gilotrif, Iresssa, 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.
11/2018	Updated background and criteria to align with NCCN recommended treatment of metastatic CNS cancer. Added NCCN Recommended Regimen review criteria. Updated references.
11/2019	Annual review. Updated references.
11/2020	Annual review. Minor change to kidney cancer section for clarity of intent. Added other EGFR sensitizing mutations to align with NSCLC section. Updated references. Added Additional Clinical Rules section.