UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1104-13
Program	Prior Authorization/Notification
Medication	Tarceva® (erlotinib)
P&T Approval Date	8/2008, 6/2009, 6/2010, 9/2010, 12/2010, 9/2011, 8/2012, 7/2013, 2/2014, 2/2015, 2/2016, 12/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023
Effective Date	2/1/2024

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 gemcitabine.[1]

In addition, the National Cancer Comprehensive Network (NCCN) also recommends Tarceva for the treatments of chordoma, brain, leptomeningeal, and spine metastases originating from 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]

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <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 pancreatic cancer

-AND-

(2) Disease is **one** of the following:

(a) Locally advanced
(b) Unresectable
(c) Metastatic

-AND-

(3) Used in combination with 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.

C. 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:

(a) Recurrent
(b) Advanced
(c) Metastatic

-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.,

S768I, L861Q, G719X)

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. 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.

E. Kidney Cancer

1. **Initial Authorization**

a. **Tarceva** will be approved based on **both** 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.

F. Central Nervous System (CNS) Cancers

1. **Initial Authorization**

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

(1) Diagnosis of brain, leptomeningeal, or spine 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
(c) Tumors are positive for a known sensitizing EGFR mutation (e.g., S768I, L861Q, G719X)

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. 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.

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H. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 September 27, 2023.

Program	Prior Authorization/Notification - Tarceva (erlotinib)
Change Control	
2/2014	Clarified indications for and added coverage for kidney cancer.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
2/2015	Annual review. Removed coverage esophageal and esophagogastric junction cancers – NCCN no longer recommends. Added coverage for leptomeningeal metastases. Clarified kidney cancer criteria. Updated background and references.
2/2016	Annual review. Revised formatting of criteria. Changed initial and reauthorization periods to 12 months. Updated references.
12/2016	Annual review. Changed member to patient in coverage criteria. 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 reference.
11/2018	Annual review. Updating background and criteria to align with NCCN recommendations for the treatment of metastatic CNS cancer. Removed “off-label” from NCCN Compendium supported indications.

	Updated background and references.
11/2019	Annual review. Added general NCCN recommendations for use criteria. Updated reference.
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.
11/2021	Annual review with no changes to clinical coverage criteria. Updated references.
11/2022	Annual review. Added coverage of advanced NSCLC and updated examples of known sensitizing EGFR mutations for NSCL and CNS cancers. Added leptomeningeal and spine metastases to background and CNS Cancers criteria. Updated reference and added state mandate footnote.
11/2023	Annual review with no changes to clinical coverage criteria. Updated references.