



CIGNA PHARMACY COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Next Review Date..... 5/15/2012
Coverage Policy Number 5010

Subject Erlotinib (Tarceva®)

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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

CIGNA covers erlotinib (Tarceva®) as medically necessary for treatment of EITHER of the following conditions:

- non-small cell lung cancer (NSCLC)
- pancreatic cancer in combination with gemcitabine

FDA Approved Indications

Non-Small Cell Lung Cancer (NSCLC)

Tarceva monotherapy is indicated for the maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. Tarceva monotherapy is indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.

Pancreatic Cancer

Tarceva in combination with gemcitabine is indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

FDA Recommended Dosing

NSCLC

The recommended daily dose for NSCLC is 150 mg taken on an empty stomach at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity occurs. There is no evidence that treatment beyond progression is beneficial.

Pancreatic Cancer

The recommended daily dose is 100 mg taken on an empty stomach at least one hour before or two hours after the ingestion of food, in combination with gemcitabine. Treatment should continue until disease progression or unacceptable toxicity occurs.

Drug Availability

25 mg tablets - round, biconvex face and straight sides, white film-coated, printed in orange with a "T" and "25" on one side and plain on the other side supplied in bottles of 30; 100 mg tablets - round, biconvex face and straight sides, white film-coated, printed in gray with "T" and "100" on one side and plain on the other side supplied in bottles of 30; 150 mg tablets - round, biconvex face and straight sides, white film-coated, printed in maroon with "T" and "150" on one side and plain on the other side supplied in bottles of 30.

General Background

Pharmacology

Erlotinib is similar to gefitinib (Iressa), which is also labeled for treatment of NSCLC. Erlotinib is a quinazoline derivative. It is a reversible inhibitor of overexpressed human epidermal growth factor receptor type 1 (HER1/EGFR) tyrosine kinase. Erlotinib inhibits the intracellular phosphorylation of tyrosine kinases by competing with ATP for binding sites. Erlotinib is approximately 60% absorbed after oral administration. Food increases bioavailability of the dose, but this is not consistent. Once absorbed, erlotinib is 93% protein bound. Erlotinib is metabolized through the cytochrome P450 system primarily by CYP3A4. The drug is mainly excreted in feces with a half-life of approximately 36 hours.

Guidelines

The National Comprehensive Cancer Network (NCCN) recommends erlotinib for the following:

NSCLC

Grade 2A

First-line therapy for patients with a known EGFR mutation; second- or third-line therapy as a single agent for progressive disease in patients with performance status (PS) 0-2; may be considered for patients with PS 3 and 4 with a known EGFR mutation.

Pancreatic Adenocarcinoma

Grade 1

In combination with gemcitabine for patients with locally advanced or metastatic disease and good performance status

Adverse Reactions

Gastrointestinal perforation (including fatalities), bullous, blistering and exfoliative skin conditions including cases suggestive of Stevens-Johnson syndrome/toxic epidermal necrolysis, in some cases fatal, and ocular disorders, including corneal perforation or ulceration have been reported during use of Tarceva. The new safety information comes from routine pharmacovigilance activities of clinical study and postmarketing reports.

The most common adverse reactions reported in clinical trials were rash and diarrhea. The rash is a class effect of all EGFR inhibitors. The severity of the rash may correlate with increased response to therapy. Elevations in liver function tests were also observed and may have been associated with liver metastases. Other infrequent adverse reactions included gastrointestinal bleeding (often associated with concomitant warfarin therapy), conjunctivitis, and keratitis. Cases of serious interstitial lung disease (ILD), including fatalities, are also associated with the use of erlotinib. Since erlotinib is metabolized predominately by CYP3A4, concomitant administration with inhibitors and inducers of this enzyme should be done with caution.

Coding/Billing Information

Note: This section is not in use.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	5/15/2008	5010	Erlotinib (Tarceva®)
Great-West Healthcare	12/2006	P04.110	Tarceva

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