DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Erlotinib Drug Quantity Management Policy – Per Rx
- Tarceva® (erlotinib tablets – Genentech, generic)

REVIEW DATE: 04/03/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, 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 SUPERSEDES 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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Erlotinib (Tarceva, generic), a tyrosine kinase inhibitor, is indicated for the following uses:[1]

- **Non-Small Cell Lung Cancer**, treatment of tumors with **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. Limitations of use: The safety and efficacy of erlotinib have not been established in patients with NSCLC whose tumors have other *EGFR* mutations. Erlotinib is not recommended for use in combination with platinum-based chemotherapy.
- **Pancreatic Cancer**, first-line treatment of patients with locally advanced, unresectable, or metastatic pancreatic cancer, in combination with gemcitabine.

Erlotinib has also been addressed in National Comprehensive Cancer Network (NCCN) guidelines for off-label use:

- **Bone Cancer:** Guidelines (version 2.2025 – February 28, 2025) note erlotinib (category 2A) as a treatment option under "Useful in Certain Circumstances" for patients with chordoma.[2] The efficacy of erlotinib was demonstrated in patients with advanced chordoma resistant to imatinib.
- **Kidney Cancer:** Guidelines (version 3.2025 – January 9, 2025) no longer recommend erlotinib monotherapy as a treatment option for patients with recurrent or advanced renal cell carcinoma (RCC) of non-clear cell histology .[6] The combination of bevacizumab with erlotinib is a treatment option (category 2A) for non-clear cell histology RCC in selected patients with advanced papillary RCC, including hereditary leiomyomatosis and renal cell cancer (HLRCC)-associated RCC under "Other Recommended Regimens".
- **Vulvar Cancer:** Guidelines (version 1.2025 – February 10, 2025) recommend erlotinib (category 2B) as a second-line or subsequent treatment option for patients with advanced, recurrent, or metastatic vulvar cancer under "Other Recommended Regimens".[4]

Dosing

For the treatment of non-small cell lung cancer (NSCLC), the recommended dose is 150 mg once daily (QD) continued until disease progression or unacceptable toxicity.[1] For the treatment of locally advanced, unresectable or metastatic pancreatic cancer, the recommended dose is 100 mg QD, in combination with gemcitabine continued until disease progression or unacceptable toxicity.

In other instances where erlotinib is recommended in guidelines, the dose is 150 mg or 100 mg QD.[2-4]

Cigarette smoking reduces the concentration of erlotinib.[1] The dose of erlotinib should be increased by 50 mg increments at 2-week intervals to a maximum dose of 300 mg. Upon cessation of smoking, the dose should immediately be reduced to the recommended dose of 100 mg or 150 mg daily. Concomitant use of erlotinib with cytochrome P450(CYP)3A4 inducers (e.g., rifampin, rifabutin, rifapentine, phenytoin, carbamazepine, phenobarbital, or St. John's Wort) decreases erlotinib concentrations.[1] When used with CYP3A4 inducers, increase the dose of erlotinib by 50 mg increments at 2-week intervals to a maximum of 450 mg as tolerated. If possible, avoid concomitant use. The dose of erlotinib should be reduced in 50 mg decrements when used with certain drugs (e.g., CYP3A4 inhibitor, CYP3A4 inhibitor and CYP1A2 inhibitor, and for certain dose-limiting toxicities).

Availability

Erlotinib (Tarceva, generic) is available as tablets in the following strengths: 25 mg, 100 mg, and 150 mg.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage dose escalation and promote dose consolidation of erlotinib. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Tarceva® (erlotinib tablets, generic)	25 mg tablets (generic only)	60 tablets	180 tablets
	100 mg tablets (brand and generic)	30 tablets	90 tablets
	150 mg tablets (generic only)	30 tablets	90 tablets

***Oncology – Erlotinib Drug Quantity Management Policy – Per Rx* product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

CRITERIA

Erlotinib 25 mg tablets (Tarceva, generic)
No overrides recommended.

Erlotinib 100 mg and 150 mg tablets (Tarceva, generic)

1. If the patient is taking a strong cytochrome P450 (CYP)3A4 inducer or smokes cigarettes, approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.
Note: CYP3A4 inducers include, but are not limited to, rifampicin, carbamazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and St. John's Wort.

REFERENCES

1. Tarceva® [prescribing information]. South San Francisco, CA: Genentech; October 2016.
2. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – February 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2025.
3. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2025.
4. The NCCN Vulvar Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – February 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date

Annual Revision	Approval duration changed from 3 years to 1 year. Policy was updated to include the existing quantity limits when the product is obtained via home delivery.	04/12/2023
Annual Revision	No criteria changes.	04/22/2024
Annual Revision	No criteria changes.	04/03/2025