DRUG QUANTITY MANAGEMENT POLICY – PER RX

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

REVIEW DATE: 04/11/2022

OVERVIEW

Erlotinib, 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:

- NCCN Bone Cancer Clinical Practice Guidelines (version 2.2022 – October 8, 2021) note erlotinib as a treatment option for patients with **chordoma** (useful in certain circumstances).[2] The efficacy of erlotinib was demonstrated in patients with advanced chordoma resistant to imatinib.
- NCCN Vulvar Cancer Clinical Practice Guidelines (version 1.2022 – October 7, 2021) recommend erlotinib for the treatment of patients with **advanced, recurrent or metastatic vulvar cancer** (squamous cell carcinoma) [other recommended regimens].[4]
- NCCN Kidney Cancer Clinical Practice Guidelines (version 4.2022 – December 21, 2021) note erlotinib as a treatment option for patients with recurrent or advanced **renal cell carcinoma** of non-clear cell histology (useful in certain circumstances).[3] The combination of bevacizumab with erlotinib is a treatment option for select patients with non-clear cell and papillary cell histology, including hereditary leiomyomatosis and renal cell carcinoma (useful in certain circumstances).

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 3 years in duration.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per Rx
Tarceva® (erlotinib tablets, generic)	25 mg tablets	60 tablets
	100 mg tablets	30 tablets
	150 mg tablets	30 tablets

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.
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 USA, Inc.; October 2016.
2. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – October 8, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 11, 2022.
3. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – December 21, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 11, 2022.
4. The NCCN Vulvar Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – October 7, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 11, 2022.