DRUG QUANTITY MANAGEMENT POLICY - ONCOLOGY PER RX

POLICY: Tarceva® (erlotinib tablets – Genentech, generics) Dispensing Limit

DATE REVIEWED: 03/09/2021

DESCRIPTION

Tarceva 25 mg tablets, generics Maximum quantity per RX = 60 tablets
Tarceva 100 mg, 150 mg tablets, generics Maximum quantity per RX = 30 tablets

Tarceva is available in 25 mg, 100 mg, and 150 mg tablets. The recommended dose for treatment of non-small cell lung cancer (NSCLC) is 150 mg once daily. The recommended dose for treatment of locally advanced, unresectable or metastatic pancreatic cancer is 100 mg once daily, in combination with gemcitabine.1 Tarceva carries a category 2A NCCN recommendation for relapsed or Stage IV renal cell carcinoma of non-clear cell histology, based on a Phase II study in papillary renal cell carcinoma that dosed Tarceva at 150 mg once daily.[3]

The dose should be reduced in 50 mg decrements, if necessary (for example, due to adverse events, hepatic impairment or drug interactions with CYP3A4 inhibitors). CYP3A4 inducers, CYP1A2 inducers, as well as cigarette smoking, may decrease erlotinib plasma concentrations.

Pretreatment with the CYP3A4 inducer rifampicin decreased erlotinib area under the curve (AUC) by approximately two-thirds to four-fifths. Use of alternative treatments lacking CYP3A4-inducing activity is strongly recommended. If an alternative treatment is unavailable, an increase in the dose of Tarceva, should be considered as tolerated at 2-week intervals while monitoring the patient's safety. The maximum dose of erlotinib studied in combination with rifampin is 450 mg. If the erlotinib dose is adjusted upward, the dose will need to be reduced immediately to the indicated starting dose upon discontinuation of rifampin or other inducers. Other CYP3A4 inducers include, but are not limited to, carbamazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and St. John's Wort; avoid these, too, if possible.

Cigarette smoking has been shown to reduce erlotinib exposure. Patients should be advised to stop smoking. If a patient continues to smoke, a cautious increase in the dose of Tarceva, not exceeding 300 mg may be considered, while monitoring the patient's safety. If the Tarceva dose is adjusted upward, the dose should be reduced immediately to the indicated starting dose upon cessation of smoking.

The objective of this program is to manage potential dose escalation and to provide a sufficient quantity for indications covered by the Oncology - Tarceva (erlotinib) Prior Authorization Policy.[2]

CRITERIA

All approvals are provided for 3 years in duration unless otherwise noted below.

Tarceva 25 mg tablets

No overrides recommended.

Tarceva 100 mg and 150 mg tablets

1. Approve 90 tablets per dispensing if the patient is taking a strong CYP3A4 inducer or smokes cigarettes. 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. Oncology - Tarceva Prior Authorization policy. Reviewed 03/11/2020.
3. Gordon MS, Hussey M, Nagle RB, et al. Phase II study of erlotinib in patients with locally advanced or metastatic papillary histology renal cell cancer: SWOG S0317. *J Clin Oncol.* 2009 Dec 1;27(34):5788-93. Epub 2009 Nov 2.