

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Iressa Drug Quantity Management Policy – Per Rx

- Iressa® (gefitinib tablets – AstraZeneca)

REVIEW DATE: 11/09/2022

OVERVIEW

Indication

Iressa, a tyrosine kinase inhibitor, is indicated for the first-line 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 as detected by an FDA-approved test.¹ The safety and efficacy of Iressa have not been established in patients with metastatic NSCLC whose tumors have *EGFR* mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

Dosing

The recommended dose of Iressa for treatment of NSCLC is 250 mg once daily (QD). Error! Reference source not found. The dose may need to be withheld due to adverse events, hepatic enzyme elevations or drug interactions with cytochrome P450 (CYP)3A4 inhibitors. CYP3A4 inducers may decrease gefitinib plasma concentrations. Therefore, the dose of Iressa should be increased to 500 mg QD, as tolerated, in patients taking strong CYP3A4 inducers (e.g., rifampicin, phenytoin, or tricyclic antidepressant). The dose should be decreased to 250 mg QD 7 days after discontinuation of the CYP3A4 inducer.

Availability

Iressa is available as 250 mg tablets in bottles containing 30 tablets each.¹

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Iressa. 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.

Automation: None.

Drug Quantity Limit

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Iressa® (gefitinib tablets)	250 mg tablets	30 tablets	90 tablets

11/09/2022

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CRITERIA

1. If the patient is taking a strong cytochrome P450 (CYP)3A4 inducer, approve 60 tablets per dispensing at retail or 180 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. Iressa® tablets [prescribing information]. Wilmington, DE: AstraZeneca; May 2021.