GEFITINIB

Generic	Brand	HICL	GCN	Exception/Other
GEFITINIB	IRESSA	25178		ROUTE = ORAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and has the patient met all of the following criteria?
   - Has tumors with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL for quantity of #2 tablets per day.**
   If no, do not approve.
   DENIAL TEXT: Our guideline for **GEFITINIB** requires that the patient has a diagnosis of 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.

RATIONALE

Promote appropriate utilization of gefitinib based on FDA approved indication and dosing.

About 85% to 90% of lung cancer is classified as NSCLC and of that population, an estimated 10% is due to an EGFR mutation. Iressa targets a specific subset of this EGFR mutation population. Although Iressa was withdrawn from the market in 2012 due to failure to demonstrate clinical benefit in NSCLC, it is now reapproved due to efficacy findings in a specific population whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

DOSAGE

The recommended dose of Iressa is 250 mg by mouth daily until disease progression or unacceptable toxicity.

Increase Iressa dose to 500 mg daily when taken concomitantly with a strong CYP3A4 inducer. Return to recommended dose of 250 mg daily 7 days after discontinuation of the strong inducer.

FDA APPROVED INDICATION

Iressa is a tyrosine kinase inhibitor 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.

Limitation of Use: Safety and efficacy of Iressa have not been established in patients whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

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GEFITINIB

REFERENCES

- Iressa [Prescribing Information]. AstraZeneca Pharmaceuticals. Wilmington, DE. July 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/15
Created: 07/15
Client Approval: 08/15
P&T Approval: 08/15