Commercial/Healthcare Exchange PA Criteria

Effective: July 03, 2023

Prior Authorization: Iressa

Products Affected: Iressa (gefitinib) oral tablets

Medication Description:
Iressa is a tyrosine kinase inhibitor (TKI) 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 a U.S. Food and Drug Administration (FDA)-approved test. The safety and efficacy of Iressa has not been established in patients whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

Iressa reversibly inhibits the kinase activity of wild-type and certain activating mutations of EGFR, preventing autophosphorylation of tyrosine residues associated with the receptor, inhibiting further downstream signaling and blocking EGFR-dependent proliferation. The binding affinity of Iressa for EGFR exon 19 deletions or exon 21 (L858R) substitution mutations is higher than the affinity for the wild-type EGFR.

Covered Uses:

1. **Non-Small Cell Lung Cancer (NSCLC)**

Exclusion Criteria:
Iressa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances.

1. NSCLC tumors with EGFR mutations other than exon 19 deletions or exon 21(L858R) substitution mutations.

Required Medical Information:

1. Confirmed NSCLC with EGFR exon 19 deletion or exon 21 (L858R) substitution mutation as detected by an FDA-approved test
2. Dose and frequency

Age Restrictions: None

Prescriber Restrictions: Prescribed by, or in consultation with, an Oncologist

Coverage Duration: 3 years

Other Criteria:

1. **Non-Small Cell Lung Cancer (NSCLC).**

A) The patient has metastatic NSCLC; AND

B) Epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutations as detected by an FDA-approved test; AND

C) Patient must have an adequate trial with Tarceva

References:

1. Iressa [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2016.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 2.2016). National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 9, 2016.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	03/15/2016
2	Revision	Required trial of Tarceva	Other Criteria	11/7/2016
3	Update	Update	Coverage Duration: Update to 3 years	07/01/2019
4	Update	Transferred to CCI template from EH	All	7/3/2023