PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Iressa Prior Authorization Policy
- Iressa® (gefitinib tablets – AstraZeneca)

REVIEW DATE: 09/02/2020

OVERVIEW

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 an FDA-approved test.[1] The safety and efficacy of Iressa have not been established in patients whose tumors have other *EGFR* mutations. Iressa binding affinity for *EGFR* exon 19 deletion or exon 21 point mutation L858R mutations is higher than its affinity for the wild-type *EGFR*.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 6.2020 – June 15, 2020) recommend Tarceva® (erlotinib tablets), Iressa, Gilotrif™ (afatinib tablets), Tagrisso™ (osimertinib tablets), and Vizimpro® (dacomitinib tablets) as first-line treatment in patients with sensitizing *EGFR*-mutation positive NSCLC (all category 1).[2] Tagrisso is noted as a "preferred" option. Tagrisso is the only agent specifically FDA-approved and recommended in guidelines (category 1) for T790M-positive tumors as subsequent therapy, after progression on first-line Tarceva, Iressa, Vizimpro, or Gilotrif.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Iressa. All approval durations are noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Iressa is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer (NSCLC).** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient has metastatic non-small cell lung cancer; AND
   - **B)** Patient meets ONE of the following conditions (i or ii):
     - **i.** Patient has epidermal growth factor receptor (*EGFR*) exon 19 deletions as detected by an approved test; OR
     - **ii.** Patient has exon 21 (L858R) substitution mutations as detected by an approved test.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Iressa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Iressa® tablets [prescribing information]. Wilmington, DE: AstraZeneca; July 2018.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 6.2020 – June 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed August 31, 2020.