PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/11/2024

OVERVIEW

Gefitinib, a tyrosine kinase inhibitor, is indicated for the first-line treatment of metastatic **non-small cell lung cancer (NSCLC)** in patients 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]

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 9.2024 – September 9, 2024) recommend testing for sensitizing *EGFR* mutations in patients with metastatic disease.[2] Patients with sensitizing *EGFR* mutations have a significantly better response to the *EGFR* tyrosine kinase inhibitors (TKIs). The most common *EGFR* mutations are exon 19 deletions and exon 21 (L858R) substitution mutations. Other less common mutations that are also sensitive to *EGFR* TKIs include L861Q, G719X, and S768I; these mutations cumulatively account for approximately 10% of all *EGFR* mutations. NCCN recommends Tagrisso® (osimertinib tablets) as the "Preferred" first-line therapy (category 1). Gefitinib and the other EGFR TKIs are listed under "Useful in Certain Circumstances" for this setting (category 1). Gefitinib is recommended under "Other Recommended" therapies (category 2A) for *EGFR* L861Q, G719X, and S768I mutations.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of gefitinib. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced or metastatic disease; AND
   - **C)** Patient has sensitizing *EGFR* mutation-positive disease; AND
     Note: Examples of sensitizing *EGFR* mutation-positive non-small cell lung cancer include the following: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X, and S768I.
   - **D)** The mutation was detected by an approved test.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of gefitinib 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; May 2021.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 9.2024 – September 9, 2024). © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 9, 2024.