PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Epidermal Growth Factor Receptor Inhibitor) – Gefitinib Prior Authorization Policy
- Iressa® (gefitinib tablets – AstraZeneca, generics)

REVIEW DATE: 09/03/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 8.2025 – August 28, 2025) recommend testing for sensitizing *EGFR* mutations in patients with metastatic disease.[2] Patients with *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.

- **Iressa® (gefitinib tablets – AstraZeneca, generics)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 *EGFR* mutation-positive disease; AND
   Note: Examples of *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 COVERED

- **Iressa® (gefitinib tablets – AstraZeneca, generics)**

is(are) considered not medically necessary for ANY other use(s); 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 8.2025 – August 15, 2025). © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 28, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date

Annual Revision	With the availability of generics for Iressa, the policy name has been changed to the generic name.	09/06/2023
Annual Revision	No criteria changes	09/11/2024
Update	04/21/2025: The policy name was changed from "Oncology – Gefitinib PA Policy" to "Oncology (Oral – Epidermal Growth Factor Receptor Inhibitor) – Gefitinib PA Policy".	N/A
Annual Revision	**Non-Small Cell Lung Cancer:** Deleted the descriptor "sensitizing" while referring to *EGFR* mutations both in criteria and in the Note.	09/03/2025

N/A – Not applicable.