

Cigna National Preferred Formulary Coverage Policy



Effective Date 1/1/2021

Next Review Date... 1/1/2022

Coverage Policy Number NPF521

Prior Authorization Oncology – Iressa® (gefitinib tablets)

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Related Coverage Resources

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. 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.

NPF Coverage Policy

Cigna covers gefitinib (Iressa®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

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

FDA Indication(s)

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 Covered

Gefitinib tablets (Iressa®) is considered experimental, investigational or unproven for ANY other use.

Background

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.

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. Accessed August 31, 2020.

Last Revision Details

Annual revision	No criteria changes	09/02/2020
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