UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1161-10
Program	Prior Authorization/Notification
Medication	Iressa® (gefitinib)
P&T Approval Date	10/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 10/2021, 10/2022, 10/2023, 10/2024
Effective Date	1/1/2025

1. Background:

Iressa® (gefitinib) is a tyrosine kinase inhibitor indicated as 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.[1] The National Cancer Comprehensive Network (NCCN) also recommends the use of Iressa in patients with NSCLC with EGFR S768I, L861Q, and/or G719X mutation positive tumors as well as patients with NSCLC with a known sensitizing EGFR mutation and associated brain metastases.[2]

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Iressa** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Non-Small Cell Lung Cancer (NSCLC)</u>

1. **<u>Initial Authorization</u>**

   a. **Iressa** will be approved based on **<u>both</u>** of the following criteria:

      (1) Diagnosis of metastatic non-small cell lung cancer (NSCLC)

      -AND-

      (2) **<u>One</u>** of the following:

(a) Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
(b) Tumors are positive for exon 21 (L858R) substitution mutations
(c) Tumors are positive for a known sensitizing EGFR mutation (e.g., exon 20 S768I mutation, exon 18 G719X mutation, exon 21 L861Q mutation).

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Iressa** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Iressa therapy

Authorization will be issued for 12 months.

C. Central Nervous System (CNS) Cancers

1. **Initial Authorization**

a. **Iressa** will be approved based on **both** of the following criteria:

(1) Diagnosis of central nervous system (CNS) cancer with metastatic lesions

-AND-

(2) Iressa is active against primary (NSCLC) tumor with a known EGFR sensitizing mutation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Iressa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Iressa therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Iressa [package insert]. AstraZeneca Pharmaceuticals LP: Wilmington DE; February 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia. Accessed September 11, 2024.

Program	Prior Authorization/Notification - Iressa (gefitinib)
Change Control	
10/2015	New program.
9/2016	Annual review. Updated criteria for NSCLC. Updated background and references.
9/2107	Annual review. No changes to the criteria.
9/2018	Annual review. Added coverage for CNS metastases. Updated background and references.
9/2019	Annual review. Updated references. Added general NCCN recommended review criteria.
9/2020	Annual review. Updated criteria for CNS cancers according to NCCN. Updated references.
10/2021	Annual review. No changes to coverage criteria. Updated references.
10/2022	Annual review. No changes to coverage criteria. Added state mandate. Updated references.
10/2023	Annual review. Updated background and list of examples of sensitizing EGFR mutations per NCCN recommendations. Updated references.
10/2024	Annual review. No changes to coverage criteria. Updated references.