UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Iressa

Program	Prior Authorization
Medication	Iressa® (gefitinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	12/2015
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

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 a known sensitizing EGFR mutation and associated brain metastases.[2]

2. Coverage Criteria:

A. <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 or recurrent non-small cell lung cancer (NSCLC)

-AND-

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

- Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g, in-frame exon 20 insertions, exon 18 G719 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.

B. 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.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Iressa** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

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.

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; May 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed Aug 4, 2019.

Program	Prior Authorization - Iressa (gefitinib)
Change Control	
Date	Change
12/2015	New guideline –combined Gilotrif, Iresssa, and Tarceva into a single policy due to similar criteria
6/2016	Updated clinical criteria to align with E&I notification policy, separated Gilotrif, Iressa, and Tarceva into separate policies to align with E&I policies, and updated policy template
9/2016	Updated criteria for NSCLC. Updated background and references.
9/2017	Annual Review. No changes to the criteria.
12/2017	Minor updates to NSCLC section based on NCCN updates. Added a section for NCCN recommended regimens to account for NCCN updates that occur outside of scheduled policy reviews.

9/2018	Added coverage for CNS metastases. Added example additional example of a known sensitizing EGFR mutation. Updated background and references.
9/2019	Annual review. Updated references.
9/2020	Annual review. Updated criteria for CNS cancers according to NCCN. Updated references. Added Additional Clinical Rules section.