## Prior Authorization Review Panel

**CHC-MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

| | |
|---|---|
| **Plan: PA Health & Wellness** | **Submission Date: 11/01/2018** |
| **Policy Number: PA.CP.PHAR.299** | **Effective Date: 10/17/2018**<br>**Revision Date: 10/17/2018** |
| **Policy Name: Gefitinib (Iressa)** | **HC Approval Date:** |

**Type of Submission – Check all that apply:**

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any changes or clarifying information for the policy below:**

This policy is being retired and replaced by the following policy:

**PA.CP.PHAR.68 Gefitinib (Iressa)**

| | |
|---|---|
| **Name of Authorized Individual (Please type or print):**<br><br>**Francis G. Grillo, MD** | **Signature of Authorized Individual:** |

# Clinical Policy: Gefitinib (Iressa)

Reference Number: PA.CP.PHAR.299
Effective Date: 01/18
Last Review Date: 11/16

Coding Implications
Revision Log

**Description**
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for Gefitinib (Iressa®) tablets for oral use.

**Policy/Criteria**
It is the policy of Pennsylvania Health and Wellness® that Iressa is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Non-Small Cell Lung Cancer** (must meet all):

1. Diagnosis of recurrent or metastatic non-small cell lung cancer (NSCLC);
2. Disease is positive for a sensitizing epidermal growth factor receptor (EGFR) mutation (exon 19 deletion or exon 21 [L858R] substitution) as detected by an FDA approved test:
3. Iressa is prescribed as first-line therapy;
4. Prescribed dose of Iressa does not exceed 250 mg per day *(Note: If Iressa is administered with a strong CYP3A4 inducer [e.g., rifampicin, phenytoin, tricyclic antidepressants], prescribed dose of Iressa does not exceed 500 mg per day).*

**Approval duration: 3 months**

**B. Other diagnoses/indications:** Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

**II. Continued Approval**

**A. Non-Small Cell Lung Cancer** (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. If Iressa is requested after disease progression on Iressa, NSCLC is characterized by any of the following *(off-label NCCN recommended use):*
   i. Asymptomatic disease (without rapid radiologic progression or threatened organ function);
   ii. Symptomatic brain lesions;
   iii. Isolated symptomatic systemic lesions;
3. Member has none of the following reasons to discontinue:
   a. Interstitial lung disease;
   b. Severe hepatic impairment (Child-Pugh C);
   c. Gastrointestinal perforation;
   d. Persistent ulcerative keratitis [ocular].

**Approval duration: 6 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellnessbenefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

**Background**

*Description/Mechanism of Action:*

The EGFR is expressed on the cell surface of both normal and cancer cells and plays a role in the processes of cell growth and proliferation. Some EGFR activating mutations (exon 19 deletion or exon 21 point mutation L858R) within NSCLC cells have been identified as contributing to the promotion of tumor cell growth, blocking of apoptosis, increasing the production of angiogenic factors and facilitating the processes of metastasis. Iressa (gefitinib) reversibly inhibits the kinase activity of wild-type and certain activating mutations of EGFR, preventing autophosphorylation of tyrosine residues associated with receptor, therapy inhibiting further downstream signaling and blocking EGFR-dependent proliferation. Gefitinib binding affinity for EGFR exon 19 deletion or exon 21 point mutation L858R mutations is higher than its affinity for the wild-type EGFR. Gefitinib also inhibits IGF and PDGF-mediated signaling at clinically relevant concentrations; inhibition of other tyrosine kinase receptors has not been fully characterized.

*Formulations:*

Iressa is available as 250 mg tablets for oral administration.

*FDA Approved Indications:*

Iressa is a tyrosine kinase inhibitor/oral tablet formulation indicated for:

- First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.
  Limitation of use:
  - Safety and efficacy of Iressa have not been established in patients with metastatic NSCLC whole tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

**Appendices**

**Appendix A: Abbreviation Key**

EGFR: epidermal growth factor receptor
IGF: insulin-like growth factor
NSCLC: non-small cell lung cancer
PDGF: platelet-derived growth factor

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J8565 | Gefitinib, oral, 250 mg |

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| Retire existing policy and replace with PA.CP.PHAR.68 Gefitinib (Iressa) | 10.18 | |

**References**

1. Iressa Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2015. Available at: http://www.azpicentral.com/iressa/iressa.pdf#page=1. Accessed November 18, 2016.
2. Gefitinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed November 18, 2016.
3. Non-small cell lung cancer (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed November 18, 2016.