

## 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<sup>®</sup> clinical policy for gefitinib (Iressa<sup>®</sup>) tablets for oral use.

### Policy/Criteria

It is the policy of Pennsylvania Health and Wellness<sup>®</sup> 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 Wellness benefit 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

### 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](http://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](http://NCCN.org). Accessed November 18, 2016.