



## PRIOR AUTHORIZATION CRITERIA

Generic/Brand: **Gefitinib (ZD1 839, Iressa)**

Therapeutic Class: tyrosine kinase inhibitor for treatment of non-small cell lung cancer (NSCLS)

### DESCRIPTION:

Gefitinib (ZD1839, Iressa<sup>®</sup>) is an oral, selective epidermal growth factor receptor-tyrosine kinase inhibitor (EGFR-TKI). The EGFR is expressed, overexpressed, or dysregulated in many cancers including breast, ovarian, non-small cell (NSCLC), mesothelioma, colorectal, and head and neck cancers. Clinically, EGFR expression has been associated with poor prognosis, development of metastasis, and resistance to chemotherapy, hormonal therapy, and radiation therapy. Gefitinib has been studied extensively in non-small cell lung cancer (NSCLC). The largest trials of gefitinib are the Iressa<sup>®</sup> Dose Evaluation in Advanced Lung Cancer 1 and 2 trials (IDEAL 1 and 2) and the Iressa<sup>®</sup> Non-small cell lung cancer Trials Assessing Combination Treatment 1 and 2 (IMPACT 1 and 2). In the IDEAL 1 trial, the tumor response was similar between previously-treated patients who received gefitinib 250 mg/day (18.4%) and 500 mg/day (19%). Preliminary analysis of the IMPACT 1 and 2 trials has shown that the addition of gefitinib to standard combination chemotherapy (i.e., gemcitabine/cisplatin or paclitaxel/carboplatin) in chemotherapy-naive patients did not offer a survival advantage.

### Indications:

Iressa (gefitinib) is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of both platinum- and docetaxel-based chemotherapies, in those patients showing benefit from current or past gefitinib.

### Criteria for approval (member must meet all of the following):

1. Member presents with a diagnosis of metastatic NSCLC
2. Member has experienced disease progression despite treatment with another antineoplastic agent including a platinum based therapy (e.g. cisplatin, carboplatin) and docetaxel.
3. Member is currently demonstrating response to therapy with gefitinib or has previously demonstrated response to therapy with gefitinib.
4. Medication is prescribed by a physician with a specialty in Oncology.

### Dosage:

Adults: 250 mg PO once daily. Higher doses do not give a better response for this indication and cause increased toxicity. In patients receiving a potent cytochrome P450 enzyme inducer, a dose increase to 500 mg PO once daily should be considered in the absence of severe adverse drug reactions, and clinical response should be monitored closely.

NOTE: As of September 15, 2005, distribution of gefitinib will be limited under a risk management plan called the Iressa<sup>®</sup> Access Program. The program will provide for renewal prescriptions for patients with benefit from gefitinib through a single mail order pharmacy. Gefitinib prescriptions for patients new to the drug and outside of a clinical trial will not be allowed.

### Length of Approval:

The length of time requested by the prescriber, but no longer than 3 months. A new request for review would need to be made when approval expires and should include patient's clinical response to therapy.

### Formulary Alternatives:

Tarceva (erlotinib)

### References:

Clinical Pharmacology, Copyright 2005, Gold Standard Multimedia, <http://www.cp.gsm.com/>

FDA Alert, June 17, 2005 Gefitinib (marketed as Iressa) Information, <http://www.fda.gov/cder/drug/infopage/gefitinib/default.htm>