

IRESSA (gefitinib)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

- 1. Metastatic non-small cell lung cancer
 - a. Tumors must have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations detected by an FDA-approved test

AND NONE of the following:

- 1. Confirmed interstitial lung disease (ILD)
- 2. Severe hepatic impairment (Child-Pugh Class C)

AND the following:

- 1. Physician agrees to withhold or discontinue the therapy if patient develops the following:
 - a. Grade 2 or higher for ALT and/or AST elevations
 - b. Worsening signs of respiratory symptoms
 - c. Persistent ulcerative keratitis of eye
 - d. Gastrointestinal perforation

Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 12 months

Prior - Approval Renewal Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:



IRESSA (gefitinib)

- 1. Metastatic non-small cell lung cancer
 - a. NO disease progression or unacceptable toxicity

AND NONE of the following has developed:

- 1. Confirmed interstitial lung disease (ILD)
- 2. Severe hepatic impairment (Child-Pugh Class C)
- 3. Gastrointestinal perforation
- 4. Persistent ulcerative keratitis of eye

AND the following:

- 1. Physician agrees to withhold or discontinue the therapy if patient develops the following:
 - a. Grade 2 or higher for ALT and/or AST elevations
 - b. Worsening signs of respiratory symptoms

Prior - Approval Renewal Limits

Same as above