I. **Medication Description**

Gefitinib (Iressa®) is the first in a class of oral, selective epidermal growth factor receptor-tyrosine kinase inhibitors (EGFR-TKI), chemotherapy drugs that inhibit an enzyme that regulates the proliferation and survival of cancer cells. EGFR mutations and dysfunctions are present in many cancers and are associated with poor prognosis, development of metastasis, and resistance to chemotherapy and radiation therapy.

II. **Position Statement**

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. **Policy**

Coverage of Iressa is provided when the following criteria are met:

- Drug is prescribed by an oncologist **AND**
- Drug is prescribed for the treatment of non-small cell lung cancer with a known sensitizing EGFR mutation **AND**
- One of the following:
  - As a single-agent (if not already given) as subsequent therapy for metastatic disease following progression on a first-line cytotoxic regimen for patients with performance status 3-4 **OR**
  - As single-agent therapy for recurrence or metastases as either
    - First-line therapy **OR**
    - Subsequent therapy following disease progression on gefitinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions

IV. **Quantity Limitations**

Coverage is available for up to FDA-approved maximum dosing.

V. **Coverage Duration**

Coverage will be provided for 6 months and may be renewed.
VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:
- The original approval criteria as outlined above are still met AND
- Positive tumor response with stabilization of disease or decrease in size of tumor or tumor spread has been shown AND
- There is an absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Available as 250mg oral tablets

VIII. Summary of Policy Changes

- 3/2011: Coverage duration changed from 12 months initial with 3 month renewal increments, to a standard 6 month approval for initial and renewed coverage; Removal of language regarding combination use with Tarceva®
- 9/9/15: policy reinstated based on renewed market availability; coverage in accordance with current NCCN treatment guidelines
- 9/15/16: policy updated to correspond with current NCCN treatment guidelines

IX. References

1. UpToDate Online, retrieved August 2016.