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 available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available for up to 30 tablets per 30 days.

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

Iressa is 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
- 10/11/17: coverage criteria updated to allow use as supported by current NCCN guidelines
- 11/1/18: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.