Iressa

Description

Iressa (gefitinib)

Background

Iressa is a tyrosine kinase inhibitor that blocks proteins that promote the development of cancerous cells with certain EGFR mutations in patients with metastatic non-small cell lung cancer (NSCLC). Lung cancer is the leading cause of cancer-related death among men and women in the U.S. and, though more common in men, the number of deaths from lung cancer in women is increasing. According to the National Cancer Institute, an estimated 221,200 Americans NSCLC is the most common type of lung cancer. Mutations in the EGFR gene are present in about 10 percent of NSCLC tumors (1).

Regulatory Status

FDA-approved indication: Iressa is a tyrosine kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21(L858R) substitution mutations as detected by an FDA-approved test (1).

Limitation of Use

Safety and efficacy of Iressa have not been established in patients whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations (1).

Iressa may cause interstitial lung disease (ILD) or ILD-like adverse reactions (e.g., lung infiltration, pneumonitis, acute respiratory distress syndrome, or alveolitis allergic). Withhold
Iressa during evaluation of patients with suspected ILD and patients who present with worsening of respiratory symptoms. Discontinue Iressa in patients with confirmed ILD (1).

Iressa may cause hepatic impairment. Obtain periodic liver function testing. Withhold Iressa for Grade 2 or higher for ALT and/or AST elevations. Discontinue for severe hepatic impairment. Permanently discontinue Iressa in patients who develop gastrointestinal perforation. Withhold Iressa for higher than Grade 3 or severe/persistent (up to 14 days) diarrhea (1).

Discontinue Iressa in patients who develop life-threatening bullous, blistering, or exfoliating lesions. Withhold Iressa for signs and symptoms of severe or worsening ocular disorders including keratitis, characterized as acute or worsening eye inflammation, lacrimation, light sensitivity, blurred vision, eye pain, and/or red eye. Discontinue if patient develops persistent ulcerative keratitis. Iressa can cause harm to fetus. Advise of potential risk to a fetus and use of effective contraception (1).

Safety and effectiveness of Iressa in pediatric patients have not been established (1).

Related policies
Gilotrif, Tagrisso, Tarceva

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Iressa may be considered medically necessary in patients that are 18 years of age and older with metastatic non-small cell lung cancer (NSCLC) and if the conditions indicated below are met.

Iressa is considered investigational in patients that are less than 18 years of age and for all other indications.

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 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 Renewal Requirements

Age
18 years of age or older

Diagnosis

Patient must have the following:

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 ALL of the following:
1. Physician agrees to withhold or discontinue the therapy if patient develops following:
   a. Grade 2 or higher for ALT and/or AST elevations
   b. Worsening signs of respiratory symptoms
Section: Prescription Drugs  Effective Date: April 1, 2019
Subsection: Antineoplastic Agents  Original Policy Date: August 7, 2015
Subject: Iressa  Page: 4 of 5

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity  90 tablets per 90 days
Duration  12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Iressa is a tyrosine kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21(L858R) substitution mutations as detected by an FDA-approved test. Iressa may cause serious side effects including interstitial lung disease, liver damage, gastrointestinal perforation, severe diarrhea and ocular disorders. The most common side effects of Iressa are diarrhea and skin reactions (including rash, acne, dry skin and pruritus, or itching). Safety and effectiveness of Iressa in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Iressa while maintaining optimal therapeutic outcomes.

References


Policy History

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>August 2015</td>
<td>Addition to PA</td>
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<tr>
<td>September 2015</td>
<td>Annual review</td>
</tr>
</tbody>
</table>
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.