Tarceva

Description

Tarceva (erlotinib)

Background
Tarceva is a cancer medication used to treat advanced non-small cell lung cancer (NSCLC) in patients with certain types of epidermal growth factor (EGFR) mutations. EGFR is a cell receptor that affects growth and spread of cancer cells, which Tarceva blocks. Tarceva can also be used as maintenance therapy in NSCLC after other types of chemotherapy medications or after a previous unsuccessful round of chemotherapy. It is also useful in the treatment of pancreatic cancer in combination with another agent (1-3).

Regulatory Status
FDA-approved indication: Tarceva is a kinase inhibitor indicated for: (1)
1. 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.
2. Maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
3. Treatment of locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.
4. First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine.

Limitations of Use:
Tarceva is not recommended for use in combination with platinum-based chemotherapy (1).
Off Label Uses: According to current oncology practice guidelines, Tarceva may also be used for: (2-3)

1. Renal cell carcinoma
2. Chordoma
3. Leptomeningeal metastases from NSCLC

Tarceva can cause severe interstitial lung disease (ILD). Withhold Tarceva and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms which may be indicative of ILD and permanently discontinue if ILD is confirmed (1).

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

Related policies
Gilotrif, Iressa, Tagrisso

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

Tarceva may be considered medically necessary in patients 18 years of age and older for the treatment metastatic non-small cell lung cancer (NSCLC), pancreatic cancer, renal cell carcinoma, recurrent chordoma, and leptomeningeal metastases from NSCLC and if the conditions indicated below are met.

Tarceva is considered investigational for patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

The patient must have ONE of the following:

1. Non-small cell lung cancer (NSCLC)

AND ONE of the following:
a. Metastatic disease with a positive EGFR mutation (exon 19 deletions or exon 21 L858R substitution mutations) detected by an FDA-approved test (e.g. cobas® EGFR Mutation Test)

b. Locally-advanced or metastatic disease and failed at least one previous chemotherapy regimen

c. Locally-advanced or metastatic disease with no progression following a platinum-based chemotherapy

2. Pancreatic cancer
   a. Tumor is locally advanced, unresectable or metastatic
   b. Used in combination with gemcitabine

3. Renal cell carcinoma
   a. Relapsed or unresectable Stage IV disease with non-clear cell histology

4. Recurrent Chordoma

5. Leptomeningeal metastases from NSCLC
   a. Positive EGFR mutation (exon 19 deletions or exon 21 L858R substitution mutations) detected by an FDA-approved test (e.g. cobas® EGFR Mutation Test)

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnosis

Patient must have ONE of the following:

1. Metastatic or locally-advanced non-small cell lung cancer (NSCLC)
2. Pancreatic cancer
3. Renal cell carcinoma
4. Recurrent Chordoma
5. Leptomeningeal metastases from NSCLC

AND the following:

a. NO disease progression or unacceptable toxicity
Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mg</td>
<td>180 tablets per 90 days OR</td>
</tr>
<tr>
<td>100 mg</td>
<td>90 tablets per 90 days OR</td>
</tr>
<tr>
<td>150 mg</td>
<td>90 tablets per 90 days</td>
</tr>
</tbody>
</table>

Maximum daily limit of any combination: 150 mg

Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Tarceva is an EGFR tyrosine kinase inhibitor that blocks proteins promoting the development of cancerous cells. It is first-line treatment for NSCLC where the patient has a specific type of EGFR mutation. It can also be used as maintenance therapy or as subsequent therapy following failure of first- or second-line chemotherapy regimens. Tarceva is also FDA-approved for use in pancreatic cancer in combination with gemcitabine (1-3).

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

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2016</td>
<td>New addition to PA</td>
</tr>
<tr>
<td>September 2016</td>
<td>Annual review</td>
</tr>
<tr>
<td>June 2017</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>September 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td></td>
<td>Addition of quantity limits</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>October 2018</td>
<td>Revised 25 mg quantity limit from 90 per 90 days to 180 per 90 days</td>
</tr>
<tr>
<td>November 2018</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>March 2019</td>
<td>Annual review and reference update</td>
</tr>
</tbody>
</table>

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.