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5.21.082

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	July 15, 2016
Subject:	Erlotinib	**Page:**	1 of 5

Last Review Date: December 13, 2024

Erlotinib

Description

Erlotinib

Background
Erlotinib is used to treat metastatic 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 erlotinib blocks. Erlotinib 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 gemcitabine (1).

Regulatory Status
FDA-approved indications: Erlotinib is a kinase inhibitor indicated for: (1)

1. 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, receiving first line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen
2. First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine.

Limitations of Use: (1)

- Safety and efficacy of erlotinib tablets have not been established in patients with NSCLC whose tumors have other EGFR mutations.
- Erlotinib is not recommended for use in combination with platinum-based chemotherapy.

Off-Label Uses: (2,3)
According to the National Comprehensive Cancer Network (NCCN) Guidelines, erlotinib may also be used for:

1. Renal cell carcinoma, relapsed or stage IV disease with non-clear cell histology
2. Chordoma
3. Leptomeningeal metastases from NSCLC with EGFR exon 19 deletion or exon 21 L858R mutation

Erlotinib can cause severe interstitial lung disease (ILD), gastrointestinal perforations and bullous and exfoliative skin disorders. Withhold erlotinib 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. Discontinue erlotinib in case of gastrointestinal perforations or bullous and exfoliative skin disorders (1).

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

Related policies
Exkivity, Gilotrif, Iressa, Tagrisso, Vizimpro

Policy

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

Erlotinib may be considered **medically necessary** if the conditions indicated below are met.

Erlotinib may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Non-small cell lung cancer (NSCLC)

AND 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)

2. Pancreatic cancer
   a. Tumor is locally advanced, unresectable or metastatic
   b. First line treatment
   c. 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

Diagnoses

Patient must have **ONE** of the following:

1. Metastatic 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

Strength	Quantity
25 mg	180 tablets per 90 days **OR**
100 mg	90 tablets per 90 days **OR**
150 mg	90 tablets per 90 days

Maximum daily limit of any combination: 150 mg

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Erlotinib is an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor that blocks proteins promoting the development of cancerous cells. It is first-line treatment for non-small cell lung cancer (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. Erlotinib is also FDA-approved for use in pancreatic cancer in combination with gemcitabine. Off-label uses include renal cell carcinoma, chordoma and leptomeningeal metastases from NSCLC. Safety and effectiveness of erlotinib in pediatric patients have not been established (1-3).

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

References

1. Erlotinib [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2019.

2. NCCN Drugs & Biologics Compendium® Erlotinib 2024. National Comprehensive Cancer Network, Inc. Accessed on October 29, 2024.
3. NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 11.2024). National Comprehensive Cancer Network, Inc. October 2024. Accessed on October 29, 2024.

Policy History

Date	Action
July 2016	New addition to PA
September 2016	Annual review
June 2017	Annual review and reference update
September 2017	Annual review Addition of quantity limits
June 2018	Annual editorial review
October 2018	Revised 25 mg quantity limit from 90 per 90 days to 180 per 90 days
November 2018	Annual review and reference update
March 2019	Annual review and reference update
June 2020	Annual review and reference update
December 2020	Annual review. Added requirement that brand Tarceva has to t/f the preferred product erlotinib
March 2021	Removed Tarceva brand from policy due to being discontinued. Changed the policy name to erlotinib. Removed locally advanced NSCL per erlotinib package insert. Removed requirement for brand Tarceva having to t/f the generic
June 2021	Annual review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.21.082
March 2024	Annual review and reference update
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.