BlueCross BlueShield Federal Employee Program

ERLOTINIB

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.
3. NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 3.2025). National Comprehensive Cancer Network, Inc. January 2025. Accessed on January 14, 2025.