ERLOTINIB

Generic	Brand	HICL	GCN	Exception/Other
ERLOTINIB	TARCEVA	26745		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet the following criteria?
    - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

    If yes, **approve for 12 months by GPID as requested with the following quantity limits:**
    - **25mg (GPID 23795): #60 tablets per 30 days.**
    - **100mg (GPID 23794): #60 tablets per 30 days.**
    - **150mg (GPID 23793): #90 tablets per 30 days.**

    If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer and meet the following criteria?
    - The requested medication will be used in combination with gemcitabine
    - The medication will be used as a first line treatment

    If yes, **approve for 12 months by GPID as requested with the following quantity limits:**
    - **25mg (GPID 23795): #60 tablets per 30 days.**
    - **100mg (GPID 23794): #60 tablets per 30 days.**
    - **150mg (GPID 23793): #90 tablets per 30 days.**

    If no, do not approve.
    DENIAL TEXT: The guideline named **ERLOTINIB (Tarceva)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC) or locally advanced, unresectable, or metastatic pancreatic cancer. In addition, the following criteria must also be met.
    For the diagnosis of metastatic non-small cell lung cancer (NSCLC), approval requires:
    - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

    For the diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer, approval requires:
    - The requested medication will be used in combination with gemcitabine
    - The medication will be used as a first line treatment

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ERLOTINIB

RATIONALE

To promote appropriate utilization of erlotinib based on FDA approved indications.

FDA approved dosage of 100mg daily for pancreatic cancer and 150mg daily for NSCLC, available as 25mg, 100mg, and 150mg tablets. Dose reduction in 50mg increments for specific adverse effects and drug interactions. Dose increase in 50mg increments for drug interactions to a maximum of 450mg daily.

FDA APPROVED INDICATIONS

Tarceva is a kinase inhibitor indicated for:

- 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-line or greater treatment.
- 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.
- Safety and efficacy of Tarceva have not been evaluated in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution.

DOSAGE & ADMINISTRATION

The recommended daily dose of Tarceva for NSCLC is 150 mg taken on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity.

The recommended daily dose of Tarceva for pancreatic cancer is 100 mg taken once daily in combination with gemcitabine. Take Tarceva on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity.

REFERENCES

- Tarceva [Prescribing Information]. Northbrook, IL. Astellas Pharma US, Inc. October 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/12/18
Created: 11/10
Client Approval: 02/18
P&T Approval: 11/16