**STANDARD COMMERCIAL DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**ERLOTINIB**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| ERLOTINIB HCL | TARCEVA, ERLOTINIB HCL | 26745 | | GPI-10 (2136002510) | |

## GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of 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
   - Tarceva (erlotinib) will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Gilotrif, Tagrisso, Iressa, Vizimpro)

   If yes, **approve for 12 months by GPID or GPI-14 as requested with the following quantity limits:**
   - **25mg: #2 per day.**
   - **100mg: #2 per day.**
   - **150mg: #3 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer and meet **ALL** of 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 or GPI-14 as requested with the following quantity limits:**
   - **25mg: #2 per day.**
   - **100mg: #2 per day.**
   - **150mg: #3 per day.**

   If no, do not approve.
   **DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ERLOTINIB (Tarceva)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
      2. Locally advanced, unresectable, or metastatic pancreatic cancer (pancreas cancer that has spread or cannot be completely removed by surgery)

   ***(Denial text continued on next page)***

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## ERLOTINIB

### GUIDELINES FOR USE (CONTINUED)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of gene mutations or permanent change in the DNA that makes up a gene) as detected by an FDA (Food and Drug Administration)-approved test
   2. You will NOT be using Tarceva (erlotinib) concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Gilotrif, Tagrisso, Iressa, Vizimpro)

C. **If you have locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires:**
   1. The requested medication will be used in combination with gemcitabine
   2. The medication will be used as a first line treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

### RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tarceva.

### 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: 07/01/22
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P&T Approval: 04/22