OSIMERTINIB

Generic	Brand	HICL	GCN	Exception/Other
OSIMERTINIB MESYLATE	TAGRISSO	42803		

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 is positive for an epidermal growth factor receptor (EGFR) T790M mutation that has been confirmed by an FDA-approved test
   - The patient has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])
   - The patient is **NOT** receiving concurrent therapy with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])

   If yes, **approve for 12 months by HICL with a quantity limit of #30 tablets per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is positive for an epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations and is confirmed by an FDA-approved test
   - The patient has **NOT** received prior systemic treatment for metastatic non-small cell lung cancer (NSCLC)

   If yes, **approve for 12 months by HICL with a quantity limit of #30 tablets per 30 days.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **OSIMERTINIB (Tagrisso)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC). In addition, **ONE** of the following criteria must be met:
   - The patient is positive for an epidermal growth factor receptor (EGFR) T790M mutation as confirmed by an FDA-approved test AND meets all of the following:
     - The patient has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])
     - The patient is **NOT** receiving concurrent therapy with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])

   (Denial text continued on next page)

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OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

- The patient is positive for an epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as confirmed by an FDA-approved test **AND** meets the following:
  - The patient has not received prior systemic treatment for metastatic non-small cell lung cancer (NSCLC)

RATIONALE
To ensure appropriate use of osimertinib (Tagrisso) consistent with FDA-approved indications.

FDA-APPROVED INDICATIONS
Osimertinib (Tagrisso) is a kinase inhibitor indicated for:
- For the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, whose disease has progressed on or after EGFR TKI therapy.
- First-line treatment of patients with metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION
The recommended dose is 80 mg orally once daily, with or without food, until disease progression or unacceptable toxicity.

AVAILABLE STRENGTHS
- 40 mg tablets
- 80 mg tablets

REFERENCES
- Tagrisso [Prescribing Information]; Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/25/18
Created: 11/15
Client Approval: 05/18
P&T Approval: 04/18