STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSIMERTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSIMERTINIB MESYLATE	TAGRISSO	42803		GPI-10 (2136006820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is being used as adjuvant therapy after tumor resection
   - 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
   - Tagrisso will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva, Iressa, Gilotrif, Vizimpro)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   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 18 years of age or older
   - Tagrisso will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva, Iressa, Gilotrif, Vizimpro)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient's tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test **AND** Tagrisso will be used as first-line treatment?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Does the patient's tumor have epidermal growth factor receptor (EGFR) T790M mutation, as detected by an FDA-approved test **AND** the patient meets the following criterion?
   - The patient's disease has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tarceva, Iressa, or Gilotrif)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

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 **OSIMERTINIB (Tagrisso)** requires the following rule(s) be met for approval:

A. You have non-small cell lung cancer (type of lung cancer)
B. You are 18 years of age or older
C. **If you have non-small cell lung cancer, approval also requires:**
    1. Tagrisso is being used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor)
    2. Your tumor is positive for an epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R (type of genes) mutations, as detected by an FDA-approved test
    3. You will NOT be using Tagrisso concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva, Iressa, Gilotrif, Vizimpro)
D. **If you have metastatic non-small cell lung cancer (cancer that has spread throughout the body), approval also requires:**
    1. You will NOT receiving another epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva, Iressa, Gilotrif, Vizimpro) together with Tagrisso
    2. You meet ONE of the following:
        a. Your tumor is positive for epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R (types of genes) mutations as confirmed by an FDA-approved test AND Tagrisso will be used as first-line treatment (initial treatment)
        b. Your tumor is positive for an epidermal growth factor receptor (EGFR) T790M (type of gene) mutation, as detected by an FDA (Food and Drug Administration)-approved test AND your disease has progressed (worsening of disease) while on or after EGFR tyrosine kinase-inhibitor therapy such as (Tarceva, Iressa, Gilotrif)

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.

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OSIMERTINIB

RATIONALE

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

REFERENCES

- Tagrisso [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 11/15
Client Approval: 05/22
P&T Approval: 04/22