Tagrisso (osimertinib)

Background
Tagrisso (osimertinib) is an oral medication to treat patients with advanced non-small cell lung cancer (NSCLC). The most common type of lung cancer, NSCLC occurs when cancer cells form in the tissues of the lung. The EGFR gene is a protein involved in the growth and spread of cancer cells. Tagrisso is kinase inhibitor indicated for patients whose tumors have a specific epidermal growth factor receptor (EGFR) mutation (T790M) and whose disease has gotten worse after treatment with other EGFR-blocking therapy, and first-line treatment of patients with metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations (1).

Regulatory Status
FDA-approved indication: Tagrisso is a kinase inhibitor indicated for: (1)
1. 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
2. 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, who have progressed on or after EGFR TKI therapy
Tagrisso can cause severe interstitial lung disease (ILD) and pneumonitis. Withhold Tagrisso and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms which may be indicative of ILD (e.g., dyspnea, cough and fever). Permanently discontinue Tagrisso if ILD is confirmed (1).

Monitor electrocardiograms and electrolytes in patients who have a history or predisposition for QTc prolongation, or those who are taking medications that are known to prolong the QTc interval. Withhold then restart at a reduced dose or permanently discontinue Tagrisso. Tagrisso can also cause cardiomyopathy. Assess left ventricular ejection fraction (LVEF) before treatment and then every 3 months thereafter (1).

Tagrisso can cause fetal harm. Advise females of potential risk to the fetus and to use effective contraception during treatment with Tagrisso and for 6 weeks after final dose. Advise males to use effective contraception for 4 months after the last dose of Tagrisso (1).

Safety and effectiveness of Tagrisso in pediatric patients have not been established (1).

Related policies
Gilotrif, Iressa, Tarceva

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tagrisso may be considered medically necessary for patients 18 years of age and older for the treatment of metastatic epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC), and if the conditions indicated below are met.

Tagrisso is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements
Age 18 years of age or older

Diagnosis
Patient must have the following:

Metastatic non-small cell lung cancer (NSCLC)

AND ONE of the following:
1. Tumor must have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an FDA-approved test
2. Tumor must have epidermal growth factor receptor (EGFR) T790M mutation-positive as detected by an FDA-approved test
   a. Disease progression following EGFR TKI (tyrosine kinase inhibitor) therapy

AND ALL of the following:
1. Left ventricular ejection fraction (LVEF) is above 50%
2. Monitor electrocardiograms and electrolytes in patients who have a history or predisposition for QTc prolongation
3. Patient must NOT have a diagnosis of clinically significant (symptomatic or debilitating) interstitial lung disease (ILD)

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Metastatic non-small cell lung cancer (NSCLC)

AND ALL of the following:
1. Left ventricular ejection fraction (LVEF) is above 50%
2. Monitor electrocardiograms and electrolytes in patients who have a history or predisposition for QTc prolongation

AND NONE of the following:
1. Disease progression or unacceptable toxicity
2. Symptoms of new or worsening interstitial lung disease (ILD)
Section: Prescription Drugs  Effective Date: April 1, 2019
Subsection: Antineoplastic Agents  Original Policy Date: December 4, 2015
Subject: Tagrisso  Page: 4 of 5

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

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<th>Quantity</th>
<th>40mg</th>
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<tr>
<td></td>
<td>80mg</td>
<td>90 tablets per 90 days</td>
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Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Tagrisso is kinase inhibitor indicated for patients whose tumors have a specific epidermal growth factor receptor (EGFR) mutation (T790M) and whose disease has gotten worse after treatment with other EGFR-blocking therapy, and first-line treatment of patients with metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations. Tagrisso may cause serious side effects, including inflammation of the lungs and injury to the heart. It also may cause harm to a developing fetus. The safety and efficacy of Tagrisso in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Tagrisso while maintaining optimal therapeutic outcomes.

References

Policy History

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Section: Prescription Drugs  Effective Date: April 1, 2019
Subsection: Antineoplastic Agents  Original Policy Date: December 4, 2015
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December 2015  Addition to PA
March 2016  Annual review
Policy number changed from 5.04.69 to 5.21.69
June 2016  Annual editorial review and reference update
Change of the assessment of left ventricular ejection fraction (LVEF) by echocardiogram or multigated acquisition (MUGA) scan before initiation and every 3 months to left ventricular ejection fraction (LVEF) is above 50% per SME
September 2016  Annual review
June 2017  Annual editorial review and reference update
Addition of age to renewal section
September 2017  Annual Review
June 2018  Annual editorial review and reference update
Addition of indication: tumor must have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an FDA-approved test
March 2019  Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.