

Osimertinib (TAGRISSO) Criteria for Use May 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to **ANY** item below is met, then the patient should NOT receive osimertinib.

- Baseline resting corrected QT interval (QTc) >470 msec obtained on more than one consecutive electrocardiogram (ECG) or risk factors ^1
- Clinically important abnormalities in cardiac rhythm, conduction or morphology on ECG
- History of Interstitial Lung Disease or clinically active Interstitial Lung Disease
- Lactating
- Pregnancy

1. Risk factors: electrolyte abnormalities, heart failure, congenital long QT syndrome, family history of long QT syndrome, concomitant medications known to prolong QTc interval

Inclusion Criteria

ONE of the following criteria must be met:

- First-line treatment of patients with metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations ^2
- In combination with pemetrexed and platinum-based chemotherapy for first-line treatment of locally advanced or metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations
- Locally advanced or metastatic non-small cell lung cancer with a documented T790M mutation
- Adjuvant therapy after tumor resection for patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations

2. NSCLC= Non-Small Cell Lung Cancer

Additional Inclusion Criteria

ALL of the following criteria must be met:

- Care is provided by a VA/VA Community Care oncology provider
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- Goals of care and role of Palliative Care consult have been discussed and documented

Additional Inclusion Criteria

- For patients who can become pregnant, counseling on potential risks vs benefits of treatment and use of effective contraception during therapy and for 6 weeks after stopping treatment.
- Patients with partners who can become pregnant, counseling on potential risks vs benefits and use of effective contraception during therapy and for 4 months after stopping therapy.

Other Justification

Prepared: July 2017; Updated November 2018; Updated March 2019; Updated Jun 2024. Contact: Mark C. Geraci, Pharm.D. BCOP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)
