

Clinical Policy Title:	osimertinib
Policy Number:	RxA.502
Drug(s) Applied:	Tagrisso®
Original Policy Date:	03/06/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (NSCLC) (must meet all):

1. Diagnosis of NSCLC;
2. Member meets one of the following (a or b):
 - a. Disease is positive for EGFR exon 19 deletion or exon 21 L858R mutation and the medication is prescribed in one of the following ways (i, ii, iii, or iv):
 - i. As adjuvant therapy after tumor resection;
 - ii. For locally advanced, unresectable (stage III) NSCLC whose disease has progressed during or following concurrent or sequential platinum-based chemoradiation therapy;
 - iii. As first-line treatment of metastatic NSCLC;
 - iv. As first-line treatment of locally advanced or metastatic NSCLC in combination with pemetrexed and platinum-based chemotherapy;
 - b. Disease is positive for T790M mutation and disease has progressed on or after EGFR TKI therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer. Version 11.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 19, 2025.
2. Ahn M-J, Chiu C-H, Cheng Y, et al. Osimertinib for patients with leptomeningeal metastases associated with egfr t790m-positive advanced nsclc: the aura leptomeningeal metastases analysis. Journal of Thoracic Oncology. 2020;15(4):637-648. Available at: [https://www.jto.org/article/S1556-0864\(19\)33854-7/fulltext](https://www.jto.org/article/S1556-0864(19)33854-7/fulltext). Accessed March 19, 2025.
3. National Comprehensive Cancer Network. Central Nervous System Cancer. Version 10.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed March 19, 2025.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Policy title table was updated. 2. Line of Business Policy Applies to was update to all lines of business. 3. Initial Approval criteria: Commercial approval duration was updated from length of benefit to 6 months. 4. Continued Therapy Approval criteria: Commercial approval duration was updated from length of benefit to 12 months. 5. Initial Approval criteria and Continued Therapy Approval criteria updated to include criteria for Leptomeningeal Metastases. 6. Initial Approval criteria and Continued Therapy Approval criteria updated to include criteria for Brain Metastases. 7. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”. 8. References were updated. 	12/03/2020	12/07/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial approval criteria I.A.4 was updated to include new criteria:"Used as first-line therapy and used in adjuvant therapy after tumor resection". 2. Initial Approval Criteria I.C.4 was updated from "EGFR T790M mutation-positive" to " Tagrisso® can be used as a single-agent treatment..." 3. Initial Approval Criteria I.C.5 added to include “If request is for limited brain metastasis, Tagrisso® can be used as....” 4. Initial Approval Criteria I.C.6. added to include “If request is for extensive brain metastasis, Tagrisso® can be used as..” 5. Continued Therapy Criteria II.A.1 , II.B.1 & II.C.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 6. References were reviewed and updated. 	09/18/2021	12/07/2021
Policy was reviewed:	08/03/2022	10/19/2022

<ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.4: "Used as first-line therapy or used in adjuvant therapy after tumor resection." replaced with "Prescribed as a single agent." 2. Initial Approval Criteria, I.A.5.a: Updated to include new request criteria <ol style="list-style-type: none"> a. Completely resected stage IB–IIIA EGFR mutation-positive NSCLC who received previous adjuvant chemotherapy or are ineligible to receive platinum based chemotherapy. 3. Initial Approval Criteria, I.B.5.a: Updated dosing criteria from 160 mg (2 tablets) per day to Dose does not exceed 160 mg (2 tablets) per day if co-administered with a strong CYP3A4 inducer (e.g., phenytoin, rifampin, carbamazepine, St. John’s wort). 4. Initial Approval Criteria, I.A, I.B, I.C: Updated approval duration criteria from 6 months to 12 months. 5. References were reviewed and updated. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 2. Removed prior age criteria. 3. Removed prior dosing criteria. 4. Updated approval duration. 5. All indications merged into one for continued therapy approval. 6. Removed reauthorization requirement for positive response to therapy 7. References were reviewed and updated. 	12/12/2023	01/01/2024
<p>Policy reviewed:</p> <ol style="list-style-type: none"> 1. Removed off label use 	4/1/2024	4/1/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prescriber restrictions. 2. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 3. References were reviewed and updated. 	10/10/2024	12/05/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Restructured initial approval criteria. 2. Added combination treatment with pemetrexed and platinum-based chemotherapy. 	03/19/2025	04/10/2025

3. Removed single agent prescribing requirement. 4. References were reviewed and updated.		
Policy reviewed	12/11/2025	12/11/2025