Clinical Policy Title:	osimertinib
Policy Number:	RxA.502
Drug(s) Applied:	Tagrisso®
Original Policy Date:	03/06/2020
Last Review Date:	04/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of recurrent, advanced or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Prescribed as a single agent;
4. Request is for one of the following (a or b):
   a. Completely resected stage IB–IIIA EGFR mutation-positive NSCLC who received previous adjuvant chemotherapy or are ineligible to receive platinum based chemotherapy;
   b. Positive for either of the following (i or ii)
      i. Sensitizing EGFR mutation (e.g., exon 19 deletion or insertion; exon 21 point mutation - L858R, L861Q; exon 18 point mutation - G719X; exon 20 point mutation - S768I);
      ii. T790M mutation with progression on or after an EGFR TKI therapy (e.g., Tarceva®, Gilotrif®, Iressa®, Vizimpro®);

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All indications:

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer. Version 4.2022. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed December 12, 2023.
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. Accessed December 12, 2023.
3. National Comprehensive Cancer Network. Central Nervous System Cancer. Version 4.2022. Available at https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed December 12, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 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: 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

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 requst criteria 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.		
Policy was reviewed: 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
Policy reviewed: 1. Removed off label use	4/1/2024	4/1/2024