Clinical Policy Title:	erlotinib
Policy Number:	RxA.616
Drug(s) Applied:	erlotinib, Tarceva®
Original Policy Date:	03/06/2020
Last Review Date:	8/28/2024
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 recurrent, advanced or metastatic NSCLC;
2. Disease is positive for a 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);
3. The requested medication may be prescribed as a single agent, in combination with Cyramza®, or in combination with bevacizumab;
4. For use in combination with bevacizumab, disease histology is nonsquamous NSCLC;
5. For Tarceva® requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration
All Lines of Business (except Medicare): 6 months

B. Pancreatic Cancer (must meet all)**:**

1. Diagnosis of locally advanced, unresectable or metastatic pancreatic cancer;
2. Prescribed in combination with gemcitabine;
3. For Tarceva requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration
All Lines of Business (except Medicare): 6 months

C. Bone Cancer (off-label) (must meet all)**:**

1. Diagnosis of recurrent chordoma;
2. Prescribed as a single agent;
3. For Tarceva requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration
All Lines of Business (except Medicare): 6 months

D. Non-clear cell Renal Cell Carcinoma (off-label) (must meet all):

1. Diagnosis of relapsed or stage IV (unresectable or metastatic) renal cell carcinoma;
2. Histology is non-clear cell;
3. For Tarceva requests, member must use generic erlotinib, unless contraindicated or clinically significant

adverse effects are experienced;

4. Prescribed as one of the following (a or b)*:
   a. Single-agent systemic therapy;
   b. In combination with bevacizumab in selected patients with advanced papillary renal cell carcinoma including hereditary leiomyomatosis and renal cell cancer (HLRCC).
   *Prescribed only in certain circumstances supported by NCCN recommendation

Approval Duration
All Lines of Business (except Medicare): 6 months

E. Central nervous system cancer (off-label) (must meet all)**:**
1. Diagnosis of limited or extensive brain metastasis from NSCLC;
2. Disease is positive for a sensitizing EGFR mutation;
3. Used as single-agent pulsatile treatment.

Approval Duration
All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (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 8.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Central Nervous System Cancers Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed August 28, 2024.
3. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf . Accessed August 28, 2024.
4. National Comprehensive Cancer Network. Bone Cancer Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed August 28, 2024.
5. National Comprehensive Cancer Network. Kidney Cancer Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/2020	03/06/2020
Policy was reviewed: 1. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by Rxadvance. 2. References were reviewed and updated.	10/07/2020	12/07/2020

Policy was reviewed: 1. Initial approval criteria I.E. updated to include off-label indication "Central nervous system cancers". 2. References were reviewed and updated.	10/18/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.5, I.A.6: Updated to include new combination therapy criteria: a. Tarceva® may be prescribed as a single agent, in combination with Cyramza®, or in combination with bevacizumab; b. For use in combination with bevacizumab: Disease histology is nonsquamous NSCLC; 2. Initial Approval Criteria, I.A.7, I.B.5, I.C.5 & I.D.5: Updated to include new trial and failure criteria For Tarceva requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced. 3. Continued Therapy Approval Criteria, II.A.3: Updated to include new trial and failure criteria For Tarceva requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced. 4. References were reviewed and updated.	09/06/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Added generic erlotinib to Drug(s) Applied. 2. Removed age restrictions. 3. Removed prescriber restrictions. 4. Removed dose restrictions. 5. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 6. Removed other reauthorization requirements including positive	8/28/2024	9/13/2024

response to therapy. 7. Updated approval duration verbiage. 8. References were reviewed and updated.		