

Clinical Policy Title:	erlotinib
Policy Number:	RxA.616
Drug(s) Applied:	erlotinib
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 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.

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;

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;

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. 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

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.

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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5, I.A.6: Updated to include new combination therapy criteria: <ol style="list-style-type: none"> a. Tarceva® may be prescribed as a 	09/06/2022	10/19/2022

<p>single agent, in combination with Cyramza®, or in combination with bevacizumab;</p> <p>b. For use in combination with bevacizumab: Disease histology is nonsquamous NSCLC;</p> <p>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.</p> <p>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.</p> <p>4. References were reviewed and updated.</p>		
Policy was reviewed.	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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 response to therapy. 7. Updated approval duration verbiage. 8. References were reviewed and updated. 	8/28/2024	9/13/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed Tarceva® from drug applied section. 2. Removed ® trial and failure criteria related to Tarceva. 	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025