Clinical Policy Title:	erlotinib
Policy Number:	RxA.616
Drug(s) Applied:	Tarceva®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
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. Age ≥ 18 years;
4. 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);
5. Tarceva® may be prescribed as a single agent, in combination with Cyramza®, or in combination with bevacizumab;
6. For use in combination with bevacizumab: Disease histology is nonsquamous NSCLC;
7. For Tarceva® requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced;
8. Request meets one of the following (a or b)*:
   a. Dose does not exceed 450 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

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

1. Diagnosis of locally advanced, unresectable or metastatic pancreatic cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with gemcitabine;
5. For Tarceva requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b)*:
   a. Dose does not exceed 450 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

C. Bone Cancer (off-label) (must meet all)**:**
1. Diagnosis of recurrent chordoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
5. For Tarceva requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 6 months
Medicaid: 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. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Histology is non-clear cell;
5. For Tarceva requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced;
6. Prescribed as (must meet 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
7. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 6 months
Medicaid: 6 months

E. Central nervous system cancer (off-label) (must meet all)**:**
1. Diagnosis of limited or extensive brain metastasis from NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is positive for a sensitizing EGFR mutation;
5. Used as single-agent pulsatile treatment;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving the medication that has been authorized by RxAdvance, or member has met initial approval criteria for the covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Tarceva requests, member must use generic erlotinib, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 450 mg per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 12 months
Medicaid: 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 September 6, 2022.
2. National Comprehensive Cancer Network. Central Nervous System Cancers Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed September 6, 2022.
3. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf . Accessed September 6, 2022.
4. National Comprehensive Cancer Network. Bone Cancer Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed September 6, 2022.
5. National Comprehensive Cancer Network. Kidney Cancer Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed September 6, 2022.

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