RXADVANCE
2 Park Central Drive
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Clinical Policy Title:	erlotinib
Policy Number:	RxA.616
Drug(s) Applied:	Tarceva®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Erlotinib (Tarceva®) is a kinase inhibitor. It is indicated for the treatment of:

- Patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.
- Patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine as first line.

Limitation(s) of use:

- Safety and efficacy of Tarceva have not been established in patients with NSCLC whose tumors have other EGFR mutations.
- Tarceva is not recommended for use in combination with platinum-based chemotherapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
erlotinib (Tarceva®)	NSCLC	150 mg PO once daily Up to 300 mg/day with concurrent tobacco smoking Up to 450 mg/day if taken with a CYP3A4 inducer	450 mg/day
	Pancreatic cancer	100 mg PO once daily Up to 300 mg/day with concurrent tobacco smoking Up to 450 mg/day if taken with a CYP3A4 inducer	450 mg/day

Dosage Forms

- Tablets: 25 mg, 100 mg, 150 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval 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. 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. 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. 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).

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. 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
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).

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 documentation supports that member is currently receiving Tarceva® for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. 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).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
EGFR: Epidermal growth factor receptor
NSCLC: Non-small cell lung cancer

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements..

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
Gemcitabine	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
    - None
- Boxed Warning(s):
    - None

APPENDIX D: General Information

- Epidermal growth factor receptor (EGFR) is expressed on the cell surface of both normal and cancer cells. In some tumor cells signaling through this receptor plays a role in tumor cell survival and proliferation irrespective of EGFR mutation status. Erlotinib reversibly inhibits the kinase activity of EGFR, preventing autophosphorylation of tyrosine residues associated with the receptor and thereby inhibiting further downstream signaling. Erlotinib binding affinity for EGFR exon 19 deletion or exon 21 (L858R) mutations is higher than its affinity for the wild type receptor. Erlotinib inhibition of other tyrosine kinase receptors has not been fully characterized.

References

1. Tarceva Prescribing Information. Northbrook, IL: OSI Pharmaceuticals LLC; October 2016. Available at http://www.gene.com/download/pdf/tarceva_prescribing.pdf. Accessed September 3, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed September 16, 2020.
3. National Comprehensive Cancer Network. Non-small Cell Lung CancerVersion 8.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf Accessed September 16, 2020.
4. National Comprehensive Cancer Network. Central Nervous System Cancers Version 2.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf Accessed September 3, 2020.
5. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma Version 1.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf . Accessed September 3, 2020.
6. National Comprehensive Cancer Network. Bone Cancer Version 1.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf Accessed September 3, 2020.
7. National Comprehensive Cancer Network. Kidney Cancer Version 1.2021. Available at https://www.nccn.org/professionals/physician_gls/default.aspx Accessed October 07, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/2020	03/06/2020
Policy was reviewed: 1. updated dosing information to rephrase “QD” to once daily 2. Commercial approval duration was updated for initial and Continued approval criteria. Removed “HIM” 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by Rxadvance. 4. Appendix B Therapeutic Alternatives, language rephrased 5. Appendix D General information added. 6. References were reviewed and updated.	10/07/2020	12/07/2020