Tarceva® (erlotinib)
(Oral)

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I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Tarceva 25mg tablets: 2 tablets per day
- Tarceva 100mg tablets: 1 tablets per day
- Tarceva 150mg tablets: 1 tablets per day

B. Max Units (per dose and over time) [Medical Benefit]:

- N/A

III. Initial Approval Criteria

- Patient is at least 18 years old; **AND**
- Not used in combination with platinum-based chemotherapy regimens; **AND**

Pancreatic cancer †

- Patient's disease is locally advanced, unresectable, or metastatic; **AND**
- Must be used in combination with gemcitabine; **AND**
- Patient must have a good performance status (ECOG 0-2)

Non–small cell lung cancer †

- Used as single agent therapy for recurrent or metastatic disease; **AND**
- Patient's disease has a known sensitizing EGFR mutation (i.e. exon 19 deletions or exon 21 (L858R) substitution mutations) as detected by an FDA-approved test (e.g. cobas® EGFR Mutation Test v2); **AND**
  - Used as first line treatment; **OR**
  - Maintenance treatment; **OR**

- Subsequent treatment following disease progression on one or more chemotherapy regimens or on erlotinib

Non-small cell lung cancer (Brain Metastases) ‡

- Patient has brain metastases; **AND**
- Patient's disease is recurrent; **AND**
- Must be used as single agent therapy; **AND**
- Used if active against primary lung tumor

Bone Cancer – Chordoma ‡

- Patient's disease is recurrent; **AND**
- Must be used as single-agent therapy

Renal Cell Carcinoma ‡

- Patient's disease must be relapsed or unresectable Stage IV; **AND**
  - Must be used as a single agent for non-clear cell histology; **OR**
  - Must be used in combination with bevacizumab to treat advanced papillary renal cell carcinoma (includes hereditary leiomyomatosis and renal cell cancer)

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria in section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: interstitial lung disease (ILD); acute renal failure; hepatotoxicity (severe changes in liver function); gastrointestinal perforations; bullous and exfoliative skin disorders; cerebrovascular accident; microangiopathic hemolytic anemia with thrombocytopenia; ocular disorders (decreased tear production, abnormal eyelash growth, keratoconjunctivitis sicca or keratitis) and hemorrhage in patients taking warfarin.

V. Dosage/Administration

Indication	Dose
Pancreatic Cancer	100 mg daily at least 1 hour before or 2 hours after food, in combination with gemcitabine
CNS-Metastatic Lesions	900-1500 mg once per week (pulsatile dosing)

All other indications	150 mg daily at least 1 hour before or 2 hours after food

VI. Billing Code/Availability Information

HCPCS:

J8999 - Prescription drug, oral, chemotherapeutic, Not Otherwise Specified
C9399- Hospital Outpatient Use ONLY

NDC:

- Tarceva 25mg tablet – 50242-0062-xx
- Tarceva 100mg tablet – 50242-0063-xx
- Tarceva 150mg tablet – 50242-0064-xx

VII. References

1. Tarceva [package insert]. South San Francisco, CA; Genentech; October 2016. Accessed March 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) erlotinib. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.
3. Eberhard DA, Johnson BE, Amler LC, Goddard AD, Heldens SL, Herbst RS, Ince WL, Jänne PA, Januario T, Johnson DH, Klein P, Miller VA, Ostland MA, Ramies DA, Sebisanovic D, Stinson JA, Zhang YR, Seshagiri S, Hillan KJ. Mutations in the epidermal growth factor receptor and in KRAS are predictive and prognostic indicators in patients with non-small-cell lung cancer treated with chemotherapy alone and in combination with erlotinib. J Clin Oncol. 2005;23(25):5900-9.
4. Massarelli E, Varella-Garcia M, Tang X, Xavier AC, Ozburn NC, Liu DD, Bekele BN, Herbst RS, Wistuba II. KRAS mutation is an important predictor of resistance to therapy with epidermal growth factor receptor tyrosine kinase inhibitors in non-small-cell lung cancer. Clin Cancer Res. 2007;13(10):2890-6.
5. Rosell R, Moran T, Queralt C, Porta R, Cardenal F, Camps C, Majem M, Lopez-Vivanco G, Isla D, Provencio M, Insa A, Massuti B, Gonzalez-Larriba JL, Paz-Ares L, Bover I, Garcia-Campelo R, Moreno MA, Catot S, Rolfo C, Reguart N, Palmero R, Sanchez JM, Bastus R, Mayo C, Bertran-Alamillo J, Molina MA, Sanchez JJ, Taron M. Screening for epidermal growth factor receptor mutations in lung cancer. N Engl J Med. 2009;361(10):958-67.

6. Giaccone G, Gallegos Ruiz M, Le Chevalier T, Thatcher N, Smit E, Rodriguez JA, Janne P, Oulid-Aissa D, Soria JC. Erlotinib for frontline treatment of advanced non-small cell lung cancer: a phase II study. Clin Cancer Res. 2006;12(20 Pt 1):6049-55.
7. Singhal N, Kotasek D, Pamis FX. Response to erlotinib in a patient with treatment refractory chordoma. Anticancer Drugs 2009;20(10):953-955
8. Grommes C, Oxnard GR, Kris MG, et al. "Pulsatile" high-dose weekly erlotinib for CNS metastases from *EGFR* mutant non-small cell lung cancer. *Neuro-Oncology*. 2011;13(12):1364-1369. doi:10.1093/neuonc/nor121.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of the pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C64.1	Malignant neoplasm of right kidney, except renal pelvis

ICD-10	ICD-10 Description
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C79.31	Secondary malignant neoplasm of brain
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.528	Personal history of other malignant neoplasm of kidney

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC