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) [NDC Unit]:

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

B. Max Units (per dose and over time) [HCPCS Unit]:

- Pancreatic Cancer: 100 mg daily
- CNS Cancer – Brain Metastases: 1,500 mg weekly
- All other indications: 150 mg daily

III. Initial Approval Criteria[1,2]

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

Pancreatic Cancer †

- Patient has locally advanced, unresectable, recurrent, or metastatic disease; **AND**
- Used in combination with gemcitabine; **AND**
- Treatment is being given in one of the following settings:
  - Used as first line therapy; **OR**
  - Used as second-line therapy for patients with disease progression following treatment with a fluoropyrimidine-based chemotherapy; **OR**

- Patient has local recurrence in the pancreatic operative bed after resection or has metastatic disease with or without local recurrence ≥ 6 months from completion of primary therapy

Non–Small Cell Lung Cancer (NSCLC) †

- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **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 or CLIA-compliant test **§**; **AND**
    - Used as single agent therapy; **AND**
      - Used as first-line treatment; **OR**
      - Used as maintenance treatment; **OR**
      - Used as subsequent treatment following disease progression on one or more chemotherapy regimens; **OR**
      - Used as continuation of therapy following disease progression on single agent erlotinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions; **OR**
    - Used in combination with bevacizumab for non-squamous disease as continuation of therapy following disease progression on erlotinib with bevacizumab for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions; **AND**
      - Patient has no history of hemoptysis; **OR**
    - Used in combination with ramucirumab; **AND**
      - Used as first-line treatment; **OR**
      - Used as continuation of therapy following disease progression on combination of erlotinib with ramucirumab for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions

Central Nervous System (CNS) Cancer (Limited or Extensive Brain Metastases) ‡

- Used as single-agent therapy; **AND**
- Patient has EGFR sensitizing mutation-positive Non-Small Cell Lung Cancer as detected by an FDA-approved or CLIA-compliant test **§**; **AND**
  - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**

- Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

Bone Cancer – Chordoma ‡

- Patient has recurrent disease; **AND**
- Used as single-agent therapy

Renal Cell Carcinoma ‡

- Patient has relapsed or metastatic (i.e., stage IV) disease; **AND**
  - Patient has non-clear cell histology disease; **AND**
    - Used as a single-agent therapy; **OR**
    - Used in combination with bevacizumab to treat advanced papillary renal cell carcinoma (includes hereditary leiomyomatosis and renal cell cancer [HLRCC])

§*If confirmed using an FDA approved assay - http://www.fda.gov/companiondiagnostics*

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

IV. Renewal Criteria[1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III ; **AND**
- Disease response with treatment as defined by 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: interstitial lung disease (ILD), acute renal failure, hepatotoxicity (severe changes in liver function), gastrointestinal perforations, bullous, blistering, and exfoliative skin disorders (e.g., Stevens-Johnson syndrome/toxic epidermal necrolysis), cerebrovascular accident, microangiopathic hemolytic anemia with thrombocytopenia, ocular disorders (e.g., decreased tear production, abnormal eyelash growth, keratoconjunctivitis sicca, or keratitis), hemorrhage in patients taking warfarin, etc.

V. Dosage/Administration[1,8]

Indication	Dose
Pancreatic Cancer	100 mg daily in combination with gemcitabine. Treatment should continue until disease progression or unacceptable toxicity occurs.
CNS Cancer – Brain Metastases	900-1500 mg once per week (pulsatile dosing)
All other indications	150 mg daily until disease progression or unacceptable toxicity occurs.

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 - Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

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 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) erlotinib. National Comprehensive Cancer Network, 2020. 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 2020.
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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

ICD-10	ICD-10 Description
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
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), Local Coverage Determinations (LCDs), and Local Coverage Article (LCAs) 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/LCA): 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.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC