Drug Policy:

Tarceva™ (Erlotinib)

POLICY NUMBER UM ONC_1043	**SUBJECT** Tarceva™ (Erlotinib)		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 3**
DATES COMMITTEE REVIEWED 01/12/11, 05/09/12, 11/01/13, 03/06/15, 03/27/15, 04/12/16, 02/08/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20, 07/08/20, 07/14/21, 11/15/21, 04/13/22, 05/11/22, 01/11/23, 02/08/23, 02/14/24	**APPROVAL DATE** February 14, 2024	**EFFECTIVE DATE** February 23, 2024	**COMMITTEE APPROVAL DATES** 01/12/11, 05/09/12, 11/01/13, 03/06/15, 03/27/15, 04/12/16, 02/08/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20, 07/08/20, 07/14/21, 11/15/21, 04/13/22, 05/11/22, 01/11/23, 02/08/23, 02/14/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Tarceva (erlotinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The member has not experienced disease progression on the requested medication AND
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
3. Additional medication(s) are not being added to the continuation request.

B. Non-Small Cell Lung Cancer (NSCLC)

1. Tarceva (erlotinib) may be used as a single agent for recurrent/metastatic, EGFR mutation positive NSCLC.

   NOTE: Per Evolent Policy, [Tarceva (erlotinib) + Cyramza (ramucirumab)] and [Tarceva (erlotinib) + Avastin (bevacizumab)/bevacizumab biosimilar products] are non-Preferred

regimens for the treatment of NSCLC. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to the Evolent recommended alternatives agents/regimens, including but not limited to regimens at http://pathways.newcenturyhealth.com.

C. Pancreatic Cancer

NOTE: Per Evolent Policy, Tarceva (erlotinib) + Gemzar (gemcitabine) is a non-preferred regimen for the treatment of advanced, unresectable, or metastatic pancreatic cancer as initial or subsequent therapy. This recommendation is based on the LAP07 Clinical Trial which demonstrated no overall survival benefit with Tarceva (erlotinib) + Gemzar (gemcitabine) compared to single agent Gemzar (gemcitabine) for patients with locally advanced pancreatic cancer. Please see reference below.

III. EXCLUSION CRITERIA

A. Disease progression while taking Tarceva (erlotinib).

B. Tarceva (erlotinib) is being used concurrently with chemotherapy.

C. Dosing exceeds single dose limit of Tarceva (erlotinib) 150 mg.

D. Treatment with Tarceva (erlotinib) exceeds the maximum duration limit of 180 (25 mg), 30 (100 mg), 30 (150 mg) tablets a month.

E. Investigational use of Tarceva (erlotinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Moore MJ, et al. National Cancer Institute of Canada Clinical Trials Group. Erlotinib plus gemcitabine compared with gemcitabine alone in patients with advanced pancreatic cancer: a phase III trial of the National Cancer Institute of Canada Clinical Trials Group. J Clin Oncol. 2007 May 20;25(15):1960-6.

B. Hammel P, et al. LAP07 Clinical Trial. Effect of Chemoradiotherapy vs Chemotherapy on Survival in Patients With Locally Advanced Pancreatic Cancer Controlled After 4 Months of Gemcitabine With or Without Erlotinib: The LAP07 Randomized Clinical Trial. JAMA. 2016 May 3;315(17):1844-53.

C. Soria JC, et al. FLAURATrial. Osimertinib in Untreated EGFR-Mutated Advanced Non-Small-Cell Lung Cancer.N Engl J Med. 2018;378(2):113.

D. Tarceva prescribing information. Genetech, Inc. 2022.

E. Clinical Pharmacology Elsevier Gold Standard 2023.

F. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

H. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.

I. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

J. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

K. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.