Evolent Clinical Guideline 3021 for Tarceva™ (erlotinib)

Guideline Number:	Applicable Codes	
Evolent_CG_3021		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
January 2011	February 2026	February 2026

TABLE OF CONTENTS

STATEMENT **2**
PURPOSE 2
INDICATIONS **2**
NON-SMALL CELL LUNG CANCER (NSCLC) 2
PANCREATIC CANCER 2
CONTRAINDICATIONS/WARNINGS **3**
EXCLUSION CRITERIA **3**
CODING AND STANDARDS **3**
CODES 3
APPLICABLE LINES OF BUSINESS 4
POLICY HISTORY **4**
LEGAL AND COMPLIANCE **4**
GUIDELINE APPROVAL 4
Committee *4*
DISCLAIMER 4
REFERENCES **5**

STATEMENT

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.

INDICATIONS

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

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

Non-Small Cell Lung Cancer (NSCLC)

- Tarceva (erlotinib) may be used as a single agent for recurrent/metastatic, EGFR mutation positive NSCLC.
- NOTE: Tarceva (erlotinib) + Cyramza (ramucirumab) and Tarceva (erlotinib) + Avastin (bevacizumab)/bevacizumab biosimilar products) are not supported by Evolent policy 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 **Evolent Pathways**.

Pancreatic Cancer

- NOTE: Tarceva (erlotinib) + Gemzar (gemcitabine) is not supported by Evolent policy 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.

CONTRAINDICATIONS/WARNINGS

- None

EXCLUSION CRITERIA

- Disease progression while taking Tarceva (erlotinib).
- Lack of EGFR mutation in members with NSCLC.
- Dosing exceeds single dose limit of Tarceva (erlotinib) 150 mg.
- Treatment with Tarceva (erlotinib) exceeds the maximum duration limit of 180 (25 mg), 30 (100 mg), 30 (150 mg) tablets a month.
- 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:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    - 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.
    - 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).
    - 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.
    - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
    - 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.

CODING AND STANDARDS

Codes

- J8999 - erlotinib

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
February 2026	• Updated verbiage from "non-preferred regimens" to "not supported by Evolent Policy" under indication section • Updated exclusion criteria • Updated references
February 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1043 Tarceva (Erlotinib) • Updated exclusion criteria
February 2024	• Removed requirement for failing Tagrisso under NSCLC indication section • Updated NCH verbiage to Evolent • Updated "continuation request" verbiage

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization

management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

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