Evolent Clinical Guideline 3057 for Gilotrif™ (afatinib)

Guideline Number: Evolent_CG_3057	**Applicable Codes**	
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STATEMENT

Purpose

To define and describe the accepted indications for Gilotrif (afatinib) 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.

Head and Neck Cancers

- NOTE: Single agent Gilotrif (afatinib) is not supported by Evolent Policy for the treatment of advanced head and neck cancers. This policy position is based on the lack of Level 1 Evidence (randomized clinical trials and/or meta-analyses) to show superior outcomes compared to Evolent recommended agents/regimens. Please refer to Evolent alternative agents/regimens recommended by Evolent, including but not limited to regimens available at **Evolent Pathways**.

Non-Small Cell Lung Cancer (NSCLC)

- Gilotrif (afatinib) may be used as monotherapy in members with advanced/recurrent/metastatic (stage IIIb or IV) NSCLC and ANY of the following:
    - As first line therapy in members with EGFR positive mutation (e.g., exon 19 deletions, exon 21 L858R, S768I, L861Q, G719X) that is negative for T790M mutation or Exon 20 insertion mutation OR
    - As second line/subsequent therapy following first line treatment with platinum containing chemotherapy, regardless of EGFR mutation status.

CONTRAINDICATIONS/WARNINGS

- None

EXCLUSION CRITERIA

- Disease progression while taking Gilotrif (afatinib).
- Gilotrif (afatinib) use in a member with advanced/metastatic Non-Small Cell Lung Cancer that is positive for the T790M mutation or EGFR Exon 20 insertion mutation.
- Concurrent use with other anti-cancer therapies.
- Dosing exceeds single dose limit of Gilotrif (afatinib) 40 mg.
- Treatment exceeds the maximum limit of 30 (20 mg), 30 (30 mg), or 30 (40 mg) tablets per month.
- Investigational use of Gilotrif (afatinib) 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 - afatinib

Applicable Lines of Business

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

POLICY HISTORY

Date	Summary
April 2026	• Updated references
April 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1258 Gilotrif (afatinib) • Updated maximum dosage form quantities in exclusion criteria • Updated references
April 2024	• Updated NCH verbiage to Evolent

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.

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