Drug Policy:

Alimta™ or Pemfexy™ (pemetrexed)

POLICY NUMBER UM ONC_1130	SUBJECT Alimta™ or Pemfexy™ (pemetrexed)	DEPT/PROGRAM UM Dept	PAGE 1 of 4
DATES COMMITTEE REVIEWED 07/22/11, 01/02/13, 03/13/13, 02/12/14, 12/16/15, 06/22/16, 04/04/17, 04/12/17, 04/11/18, 04/10/19, 12/11/19, 12/19/20, 03/11/20, 06/10/20, 02/10/21, 03/10/21, 09/08/21, 11/15/21, 03/09/22, 05/11/22	APPROVAL DATE May 11, 2022	EFFECTIVE DATE May 27, 2022	COMMITTEE APPROVAL DATES 07/22/11, 01/02/13, 03/13/13, 02/12/14, 12/16/15, 06/22/16, 04/04/17, 04/12/17, 04/11/18, 04/10/19, 12/11/19, 03/11/20, 06/10/20, 02/10/21, 03/10/21, 09/08/21, 11/15/21, 03/09/22, 05/11/22
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	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 Alimta or Pemfexy (pemetrexed) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR

2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways (http://pathways.newcenturyhealth.com/) when applicable, otherwise shall follow NCH drug policies AND

4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND

5. When applicable, generic alternatives are preferred over brand-name drugs AND

6. When there is a documented drug shortage, disease progression, contraindication, or confirmed intolerance to a Preferred drug/regimen, per NCH Policy and Pathway, the available alternative product may be used if deemed medically appropriate and the indication is listed in a standard reference compendia or accepted peer review literature. For a list of current drug shortages, please refer to FDA drug shortage website in the reference section.

B. Non-Small Cell Lung Cancer (NSCLC)

1. The member has recurrent or metastatic non-squamous NSCLC and Alimta or Pemfexy (pemetrexed) may be used for ANY of the following:

   a. First line therapy in combination with carboplatin/cisplatin OR

   b. First line in combination with carboplatin/cisplatin + Keytruda (pembrolizumab) for EGFR negative and ALK negative disease OR

   c. Subsequent therapy in combination with carboplatin/cisplatin OR

   d. Subsequent therapy as a single agent OR

   e. Maintenance therapy as a single agent after response or stable disease following first-line therapy or maintenance therapy in combination with pembrolizumab following first-line therapy with [pembrolizumab + pemetrexed + cisplatin/carboplatin].

2. NOTE: Per NCH Pathway & NCH Policy, [Bevacizumab + Carboplatin/Cisplatin + Pemetrexed] followed by maintenance [Bevacizumab + Pemetrexed] is a non-Preferred regimen. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to NCH Preferred regimens for the initial treatment of NSCLC. Please refer to NCH Pathway for the preferred treatments recommended for use in the above setting.

C. Malignant Pleural Mesothelioma

1. The member has malignant pleural mesothelioma and Alimta or Pemfexy (pemetrexed) may be used in ONE of the following:

   a. In combination with cisplatin/carboplatin for stage I-IIIA clinically operable disease OR

   b. As first line therapy for unresectable or metastatic disease as a single agent or in combination with cisplatin or carboplatin with or without bevacizumab OR

   c. As subsequent therapy as a single agent (if not previously used in the first line setting).

III. EXCLUSION CRITERIA

A. Dosing exceeds single dose limit of Alimta or Pemfexy (pemetrexed) 500 mg/m^2.

B. Disease progression on Pemetrexed containing regimen.

C. Investigational use of Alimta or Pemfexy (pemetrexed) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence

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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 definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.

4. Whether the experimental design, in light of 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

B. Review – Utilization Management Department

C. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Alimta prescribing information. Eli Lilly and Company. Indianapolis, IN 2021.

B. Pemfexy prescribing information. Eagle Pharrnaceuticals, Inc. Woodcliff Lake, NJ 2022.

C. Clinical Pharmacology Elsevier Gold Standard 2022.

D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2022.

E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2022.

F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs . Bethesda, MD 2022.

G. 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.

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

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