Department:	Pharmacy Management	**Original Approval:**	12/24/2015
Policy #:	PM104	**Last Approval:**	12/12/2018
Title:	Pemetrexed (Alimta®)		
Approved By:	UM Committee		

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Pemetrexed (Alimta): History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Age -Medication list (current and past) to include all chemotherapy agents -Labs/diagnostics -Age -Weight -Height -Renal function as measured by eCrCl.

BACKGROUND

Alimta is a folate analog metabolic inhibitor that disrupts folate-dependent metabolic processes essential for cell replication.[1] Alimta is indicated for locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) as initial treatment in combination with cisplatin; as maintenance treatment of patients whose disease has not progressed after four cycles of platinum-based first-line chemotherapy; or after prior chemotherapy as a single agent.[1] Alimta is not indicated for the treatment of patients with squamous cell NSCLC. Alimta in combination with cisplatin is also indicated for treatment of patients with malignant pleural mesothelioma (MPM) whose disease is unresectable or who are otherwise not candidates for curative surgery.

Concomitant vitamin supplementation and premedication are required with Alimta therapy to reduce toxicity.[1] Supplementation with oral folic acid 400 mcg to 1,000 mcg once daily should begin 7 days before the first dose of Alimta and continued during the full course of therapy and for 21 days after the last dose of Alimta. Intramuscular vitamin B12 (cyanocobalamin) 1 mg is required one week prior to the first dose of Alimta and every 3 cycles thereafter; subsequent vitamin B12 injections may be given the same day as treatment with Alimta. Premedication is required with oral dexamethasone 4 mg twice daily the day before, the day of, and the day after Alimta is given to reduce the risk of severe skin rash.

Alimta is available as a lyophilized powder in single-use 100 mg and 500 mg vials.[1] The 100 mg vials are reconstituted with 4.2 mL of 0.9% sodium chloride (NaCl) injection and the 500 mg vials are reconstituted with 20 mL of 0.9% NaCl injection. The final solution will contain 25 mg of Alimta per mL. The appropriate amount of reconstituted Alimta is diluted with 0.9% NaCl so the total volume is 100 mL. Alimta is given as an intravenous infusion over 10 minutes.

DEFINITIONS

None.

INDICATIONS/CRITERIA

Medicaid Members	***Continue to criteria for approval below.***
Medicare Members	***Step-utilization of Part D drugs not required.***

Coverage of Alimta is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Non-Small Cell Lung Cancer (NSCLC).

Criteria. *The patient must meet the following criteria (A, B, AND C)*:

- **A)** Alimta is prescribed by or in consultation with an oncologist; AND
- **B)** The patient has non-squamous cell non-small cell lung cancer (NSCLC);[1-2] AND
- **C)** The patient meets ONE of the following criteria (i or ii):
  - **i.** Alimta is being used for chemoradiation, perioperative, neoadjuvant, or adjuvant therapy; OR
  - **ii.** Alimta is being used for recurrent or metastatic disease and the following conditions are met (a ,b, or c):

    a) If the NSCLC tumor is positive for any of the targetable mutations (e.g., epidermal growth factor receptor [*EGFR*] mutation, anaplastic lymphoma kinase [*ALK*] fusions, ROS proto-oncogene 1 [*ROS1*]), at least one of the targeted therapy has been tried and Alimta is used as subsequent therapy; OR

    b) If the NSCLC tumor is *BRAF V600E* mutation-positive, Alimta is used as either first-line therapy or subsequent therapy; OR

    c) The NSCLC tumor is negative or unknown for targetable mutations (e.g., *EGFR*, *ALK, ROS1*, *BRAF)* and the patient meets ONE of the following criteria (1 or 2):

    (1) Alimta is used as initial therapy in combination with platinum chemotherapy (cisplatin or carboplatin) either with or without Keytruda® (pembrolizumab intravenous injection); OR

    (2) Alimta is used as subsequent therapy and is used either as a single agent or in combination with other agents.

Dosing in Non-Squamous NSCLC in Adults.

Dosing must meet the following: 500 mg per m^2 intravenous infusion on Day 1 of each 21-day cycle.[1-2,5-7]

Note: Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician. Dosing modifications are recommended in the prescribing information and treatment may be delayed to allow time for recovery.[1] Dosing modifications are dependent on diagnosis, concomitant therapy, and toxicity. Alternate dosing will be assessed individually on a case-by-case basis.

Initial Approval/Extended Approval. Initial and Extended Approval: 1 year

Duration of Therapy in Non-Squamous NSCLC. Determined by the prescriber. Patient must meet criteria and dosing above.
Note: Usual duration is 4 to 6 cycles for initial or subsequent therapy. As maintenance therapy, Alimta may be continued until disease progression or unacceptable toxicity.

Labs/Diagnostics. None required.
Note: If Alimta is requested for *BRAF V600E* mutation-positive NSCLC, then targeted mutation testing may be needed as per above criteria.

2. Mesothelioma.

Criteria. *The patient must meet the following criteria (A AND B):*
- **A)** Alimta is prescribed by or in consultation with an oncologist; AND
- **B)** The patient meets ONE of the following criteria (i or ii):
  - **i.** Alimta is being used for malignant pleural mesothelioma (MPM);[1,4] OR
  - **ii.** Alimta is being used for malignant peritoneal mesothelioma, pericardial mesothelioma, or tunica vaginalis testis mesothelioma.[4]

Dosing in Mesothelioma in Adults. *Dosing must meet the following*: 500 mg per m^2 as an intravenous infusion on Day 1 of each 21-day cycle.[1]

Alternate dosing will be assessed individually on a case-by-case basis.

Note: Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician. Dosing modifications are recommended in the prescribing information and treatment may be delayed to allow time for recovery.[1]

Initial Approval/Extended Approval.
Initial and Extended Approval. 1 year

Duration of Therapy in Mesothelioma.
Determined by the prescriber. Patient must meet criteria and dosing above.
Note: Alimta may be continued until disease progression or unacceptable toxicity.

Labs/Diagnostics. None required.

Other Uses with Supportive Evidence
3. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.

Criteria. *The patient must meet the following criteria (A, B, AND C):*
- **A)** Alimta is prescribed by or in consultation with an oncologist; AND
- **B)** The patient has persistent or recurrent disease; AND

C) At least one other systemic chemotherapy regimen has been tried (e.g., docetaxel or paclitaxel plus carboplatin).

Dosing in Ovarian, Fallopian Tube, or Primary Peritoneal Cancer in Adults. *Dosing must meet the following*: 500 mg per m^2 as an intravenous infusion on Day 1 of each 21-day cycle.[16]Alternate dosing will be assessed individually on a case-by-case basis.

Note: Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician. Dosing modifications are recommended in the prescribing information for NSCLC and MPM, and treatment may be delayed to allow time for recovery.[1] The NCCN clinical practice guidelines on ovarian cancer including fallopian tube cancer and primary peritoneal cancer (version 2.2018) recommends Alimta as single agent therapy for persistent disease or recurrence(category 2A).[17] Many other single agent cytotoxic therapies are also potentially active for recurrence of disease (e.g., Hexalen® [altretamine capsules], capecitabine, cyclophosphamide, doxorubicin, ifosfamide, irinotecan, paclitaxel).

Initial Approval/Extended Approval. Initial and Extended Approval. 1 year

Duration of Therapy in Ovarian, Fallopian Tube, or Primary Peritoneal Cancer. Limited information is available. Therapy may be extended based on the opinion of the prescribing physician.

In one Phase II trial, patients who received Alimta 500 mg/m^2 every 3 weeks as a single agent, the median number of cycles administered was four (range, 1 to 11).[16] The overall response rate (ORR) was 9.3% (95% CI: 2.6%, 22.1%) in patients receiving the 500 mg/m^2 dose and 10.4% (95% CI: 3.5%, 22.7%) in patients receiving 900 mg/m^2. In one Phase II trial, Alimta 500 mg/m^2 every 21 days in combination with carboplatin was used to treat patients (n = 45) with platinum-sensitive epithelial ovarian, peritoneal serous, or fallopian tube cancer.[18] The ORR was 51.1% (n = 23/45 partial responses [PRs]). The mean number of cycles per patient was 5.34 cycles (range, one to eight).

Lab/Diagnostics. None required.

4. Primary Central Nervous System (CNS) Lymphoma [PCNSL].

Criteria. *The patient must meet the following criteria (A,B, and C):*

A) Alimta is prescribed by or in consultation with an oncologist; AND

B) The patient has relapsed or refractory disease; AND

C) The patient has received at least one prior therapy (e.g., methotrexate-based regimen, high-dose chemotherapy plus stem cell rescue).

B)

Dosing in PCNSL in Adults. *Dosing must meet the following*: 900 mg per m^2 as an intravenous infusion every 21 days.[19]

Alternate dosing will be assessed individually on a case-by-case basis.

Note: Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician.

The NCCN clinical practice guidelines on CNS cancers (version 1.2018) recommend Alimta as one of the treatments for relapsed or refractory disease in patients with PCNSL.[20]

In one Phase II study, patients (n = 11) with relapsed or refractory PCNSL received single-agent Alimta 900 mg/m^2 every 3 weeks until complete remission, progression, or toxicity.[19] One cycle was six weeks. The dose of Alimta was chosen to optimize CNS penetration. Ten of the patients had failed prior therapy with high-dose MTX. The median number of treatment cycles of Alimta given was five (range, 1 to 7). The ORR was 55% with four CRs and two PRs. Six-month progression-free survival (PFS) was 45%, median PFS was 5.7 months, and median overall survival was 10.1 months. **Dosing in PCNSL in Adults.** Limited information is available. Determined by the prescriber. Patient must meet criteria and dosing above.

Note: Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician. Dosing modifications are recommended in the prescribing information for NSCLC and MPM, and treatment may be delayed to allow time for recovery.[1] Dosing modifications are dependent on diagnosis, concomitant therapy, and toxicity. Alternate dosing will be assessed individually on a case-by-case basis.

Initial Approval/Extended Approval. Initial and Extended Approval: 1 year

Duration of Therapy in PCNSL. Limited information is available. Determined by the prescriber. Patient must meet criteria and dosing above.

Lab/Diagnostics. None required.

5. Thymic Carcinoma or Thymoma.

Criteria. *The patient must meet the following criteria (A AND B):*

A) Alimta is prescribed by or in consultation with an oncologist; AND

B) The patient has tried chemotherapy with regimens that include, for example, cisplatin plus doxorubicin, cisplatin plus etoposide, carboplatin plus paclitaxel.

The NCCN clinical practice guidelines on thymomas and thymic carcinomas (version 2.2018) recommends single agent Alimta as a second-line chemotherapy for thymic carcinoma or thymoma (category 2A).[23] First-line combination chemotherapy regimens include cisplatin- or carboplatin-based therapy.

In one Phase II trial, previously treated patients with thymomas (n = 16) or thymic carcinomas (n = 11) received Alimta 500 mg/m^2 every 3 weeks for a maximum of 6 cycles.[21] In 23 patients who were fully evaluable there were two CRs and two PRs. All of these patients had thymomas. In one retrospective

analysis, patients (n = 16) with unresectable, invasive, recurrent or metastatic thymoma (n =6) or thymic (n = 10) carcinomas who had received Alimta 500 mg/m^2 every 3 weeks as second-line therapy and beyond were reviewed.[22] The median number of cycles was six. In the patients with thymoma, one patient had a PR and five patients had stable disease, and at a median follow-up of 21.2 months, the PFS was 13.8 months and median overall survival was 20.1 months. In patients with thymic carcinoma one patient had a PR, five patients had stable disease, and four patients had progressive disease, and at a median follow-up of 13.5 months, the median PFS was 6.5 months and the median overall survival was 12.7 months.

Dosing in Thymic Carcinoma or Thymoma in Adults. *Dosing must meet the following*: 500 mg per m^2 as an intravenous infusion on Day 1 of each 21-day cycle.[30-31]

Note: Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician. Dosing modifications are dependent on diagnosis, concomitant therapy, and toxicity.

Initial Approval/Extended Approval.*Initial and Extended Approval.* 1 year

A) .

Duration of Therapy in Thymic Carcinoma or Thymoma. Limited information is available. Determined by the prescriber. Patient must meet criteria and dosing above.

Lab/Diagnostics. None required

6. Urothelial Carcinoma.

Criteria. *The patient must meet the following criteria (A, B, AND C):*

A) Alimta is prescribed by or in consultation with an oncologist; AND

B) The patient has locally advanced or metastatic urothelial carcinoma; AND

Alimta is used as subsequent therapy after disease progression on at least one prior therapy (e.g., cisplatin- or carboplatin-containing regimen, immunotherapy [Keytruda® {pembrolizumab injection}, Tecentriq® {atezolizumab injection}, Imfinzi™ {durvalumab injection}, Bavencio® {avelumab injection}], gemcitabine plus paclitaxel, ifosfamide, methotrexate, Abraxane® [paclitaxel albumin-bound]).

The NCCN clinical practice guidelines on bladder cancer (version 5.2018) recommend Alimta as a single agent for urothelial carcinoma of the bladder for clinical Stage T4b or T2-T4a, N1-3 disease, or for recurrence post cystectomy or for metastatic disease as subsequent systemic therapy.[26] Alimta is also recommended as a single agent for the following: recurrent or metastatic disease as subsequent systemic therapy for urothelial carcinoma of the urethra; as subsequent systemic therapy for metastatic upper genitourinary tract tumors; or for subsequent systemic therapy for metastatic urothelial carcinoma of the prostate.

In one Phase II multicenter trial, patients (n = 47) previously treated with one prior chemotherapy regimen for locally advanced or metastatic urothelial carcinoma or who had relapsed within 1 year of adjuvant or neoadjuvant therapy received single-agent Alimta 500 mg/m^2 every 3 weeks.[24] Alimta

was given until disease progression, unacceptable toxicity, or a request to discontinue therapy. The ORR was 27.7% with 6.4% (n = 3/47) CRs and 21.3% (n = 10/47) PRs. Ten patients had stable disease. Median overall survival was 9.6 months (95% CI: 5.1, 14.6). Median duration of response was 5.0 months. In one Phase II study conducted in Korea, patients (n = 42) with recurrent or metastatic urothelial carcinoma received Alimta 500 mg/m^2 with cisplatin every 3 weeks.[25] Seven patients had received platinum-based adjuvant or neoadjuvant chemotherapy. No patients had a CR and 64.3% of patients (n = 27/42) had a PR. Median PFS was 6.9 months and median overall survival was 14.4 months. The median number of cycles given was eight (range, 1 to 8).

Dosing in Urothelial Carcinoma in Adults. *Dosing must meet the following*: 500 mg per m^2 as an intravenous infusion on Day 1 of each 21-day cycle.[24-25]

Note: Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician.
Initial Approval/Extended Approval.*Initial and Extended Approval.* 1 year

Duration of Therapy in Urothelial Carcinoma. Limited information is available. Determined by the prescriber. Patient must meet criteria and dosing above.

In one Phase II trial, the median number of cycles administered was three (range 1 to 27 cycles).[24]

Lab/Diagnostics. None required

7. **Other Cancer-Related Indications.** Forward to the Medical Director for review on a case-by-case basis. An example of other indications supported in the *NCCN Compendium* with a category 2B recommendation includes: cervical cancer.[3]

Waste Management for All Indications.
Dosing is based on body surface area (m^2). The dose should be calculated and the number of vials needed assessed.

Conditions Not Recommended for Approval
Alimta has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

SPECIAL CONSIDERATIONS

None.

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

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3. The NCCN Drugs & Biologics Compendium. © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 24, 2018. Search term: pemetrexed.
4. The NCCN Malignant Pleural Mesothelioma Clinical Practice Guidelines in Oncology (Version 2.2018 – February 26, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 27, 2018.
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7. Rodrigues-Pereira J, Kim JH, Magallanes M, et al. A randomized phase 3 trial comparing pemetrexed/carboplatin and docetaxel/carboplatin as first-line treatment for advanced, nonsquamous non-small cell lung cancer. *J Thorac Oncol.* 2011;6:1907-1914.
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OTHER REFERENCES UTILIZED

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CFR		
WAC	WAC 284-43-2050	
RCW		
Contract Citation	☐ WAH	
	☐ IMC	
	☐ MA	
Other Requirements		
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
12/23/2015	New	Kelly Force; Yusuf Rashid, RPh
12/24/2015	Approval	MMLT
01/11/2017	No revisions	Fran McGaugh
01/12/2017	Approval	MMLT
07/24/2017	Criteria completely updated and revised	Michael Sporck, Pharmacy Intern Sophia Yun, PharmD
07/25/2017	Approved	MMLT

03/09/2018	Reassigned from UM to PM	Cindy Bush
04/23/2018	Transferred to new template	Cindy Bush
05/16/2018	Revised	Jennifer Farley, PharmD
06/14/2018	Approval	UM Committee
11/20/2018	Policy update due to annual ESI policy update	Jennifer Farley, PharmD
12/12/2018	Approval	UM Committee