

Reference number(s)
1900-A

## SPECIALTY GUIDELINE MANAGEMENT

### ALIMTA (pemetrexed)

#### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### A. FDA-Approved Indications

1. Non-squamous non-small cell lung cancer (NSCLC)
  - a. Alimta is indicated in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations.
  - b. Alimta is indicated in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC).
  - c. Alimta is indicated as a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
  - d. Alimta is indicated as a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy.

*Limitations of use:* Alimta is not indicated for the treatment of patients with squamous cell, non-small cell lung cancer (NSCLC).

2. Mesothelioma  
Alimta is indicated, in combination with cisplatin, for the initial treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

##### B. Compendial Uses

1. Bladder cancer
2. Malignant pleural mesothelioma
3. Nonsquamous non-small cell lung cancer (NSCLC)
4. Ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, grade 1 endometrioid carcinoma, low-grade serious carcinoma/ovarian borderline epithelial tumor (low malignant potential) with invasive implants, and mucinous carcinoma
5. Primary central nervous system (CNS) lymphoma
6. Thymomas and thymic carcinomas
7. Malignant peritoneal mesothelioma
8. Pericardial mesothelioma
9. Tunica vaginalis testis mesothelioma
10. Cervical cancer

All other indications are considered experimental/investigational and not medically necessary.

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## II. EXCLUSIONS

Coverage will not be provided for members with squamous cell NSCLC.

## III. CRITERIA FOR INITIAL APPROVAL

### A. Bladder Cancer

Authorization of 6 months may be granted for treatment of locally advanced, metastatic, or relapsed transitional cell urothelium cancer, as second-line treatment.

### B. Malignant Pleural Mesothelioma (MPM)

Authorization of 6 months may be granted for treatment of MPM when any of the following criteria are met:

1. Alimta will be used as a single agent or in combination with cisplatin or carboplatin; or
2. Alimta will be used in combination with bevacizumab and either cisplatin or carboplatin.

### C. Non-Small Cell Lung Cancer (Non-Squamous Histology)

Authorization of 6 months may be granted for treatment of non-squamous non-small cell lung cancer.

### D. Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer

Authorization of 6 months may be granted for treatment of persistent or recurrent epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, grade 1 endometrioid carcinoma, low-grade serious carcinoma/ovarian borderline epithelial tumor (low malignant potential) with invasive implants, or mucinous carcinoma, as single agent therapy.

### E. Primary Central Nervous System (CNS) Lymphoma

Authorization of 6 months may be granted for treatment of primary CNS lymphoma, as a single agent.

### F. Thymomas and Thymic Carcinomas

Authorization of 6 months may be granted for treatment of thymoma or thymic carcinoma, as a single agent.

### G. Malignant Peritoneal Mesothelioma (MPeM)

Authorization of 6 months may be granted for treatment of MPeM.

### H. Pericardial Mesothelioma

Authorization of 6 months may be granted for treatment of pericardial mesothelioma.

### I. Tunica Vaginalis Testis Mesothelioma

Authorization of 6 months may be granted for treatment of tunica vaginalis testis mesothelioma.

### J. Cervical Cancer

Authorization of 6 months may be granted for treatment of persistent or recurrent cervical cancer.

## IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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## V. REFERENCES

1. Alimta [package insert]. Indianapolis, IN: Lilly USA, LLC; January 2019.
2. The NCCN Drugs & Biologics Compendium 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed July 14, 2021.
3. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed July 14, 2021.