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 EFRG 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 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, primary carcinoma of the urethra, upper genitourinary (GU) tract tumors, and urothelial carcinoma of the prostate
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, and primary peritoneal cancer
5. Primary central nervous system (CNS) lymphoma
6. Thymomas and thymic carcinomas
7. Malignant peritoneal mesothelioma
8. Cervical cancer

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS
Coverage will not be provided for members with any of the following exclusions: Squamous cell NSCLC

III. CRITERIA FOR INITIAL APPROVAL

A. Bladder Cancer, Primary Carcinoma of the Urethra, Upper Genitourinary Tract Tumors, and Urothelial Carcinoma of the Prostate

1. Bladder Cancer
   Authorization of 6 months may be granted for treatment of bladder cancer, as a single agent as subsequent therapy.

2. Upper Genitourinary Tract Tumors and Urothelial Carcinoma of the Prostate
   Authorization of 6 months may be granted for treatment of metastatic upper genitourinary tract tumors or urothelial carcinoma of the prostate, as a single agent as subsequent therapy.

3. Primary Carcinoma of the Urethra
   Authorization of 6 months may be granted for treatment of recurrent or metastatic primary carcinoma of the urethra, as a single agent as subsequent therapy.

B. Malignant Pleural Mesothelioma (MPM)
   Authorization of 6 months may be granted for treatment of MPM in members 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 in members when Alimta will be used in any of the following regimens:
   1. As a single agent; or
   2. Alimta in combination with cisplatin or carboplatin; or
   3. Alimta in combination with pembrolizumab or bevacizumab; or
   4. Alimta in combination with pembrolizumab and either cisplatin or carboplatin; or
   5. Alimta in combination with bevacizumab and either cisplatin or carboplatin.

D. Epithelial 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, or primary peritoneal cancer, as single agent therapy.

E. Primary Central Nervous System (CNS) Lymphoma
   Authorization of 6 months may be granted for treatment of relapsed or refractory 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 for second-line therapy.

G. Malignant Peritoneal Mesothelioma (MPeM)
   Authorization of 6 months may be granted for treatment of MPeM.

H. 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 who have not experienced disease progression or an unacceptable toxicity.

V. REFERENCES