

Alimta (pemetrexed)

Line(s) of Business:

HMO; PPO; QUEST Integration
Medicare Advantage

Original Effective Date:

09/01/2007

Current Effective Date:

03/01/2018

POLICY

A. 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 contraindications or exclusions to the prescribed therapy.

FDA-Approved Indications

- Nonsquamous non-small cell lung cancer (NSCLC)
 - Alimta is indicated in combination with cisplatin therapy for the initial treatment of patients with locally advanced or metastatic nonsquamous NSCLC.
 - Alimta is indicated for the maintenance treatment of patients with locally advanced or metastatic nonsquamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
 - Alimta is indicated as a single agent for the treatment of patients with locally advanced or metastatic nonsquamous NSCLC after prior chemotherapy.
 - Malignant pleural mesothelioma (MPM)
 - Alimta in combination with cisplatin is indicated for the treatment of patients with MPM whose disease is unresectable or who are otherwise not candidates for curative surgery.
- Limitations of use
 - Alimta is not indicated for the treatment of patients with squamous cell NSCLC.

Compendial Uses

- Bladder cancer, primary carcinoma of the urethra, upper genitourinary (GU) tract tumors, and urothelial carcinoma of the prostate
- Malignant pleural mesothelioma
- Non-squamous cell NSCLC
- Ovarian cancer (epithelial histology), fallopian tube cancer, and primary peritoneal cancer
- Primary central nervous system (CNS) lymphoma
- Thymoma and thymic carcinoma

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Current oncology notes and clinical notes that include the history of previous treatments and any pertinent pathology reports and/or imaging studies.
- Where applicable, results of EGFR and ALK mutation testing

C. PRESCRIBER RESTRICTION

The medication must be prescribed by, or in conjunction with, an oncologist

D. EXCLUSIONS

- Squamous cell NSCLC

E. CRITERIA FOR APPROVAL

All members must receive concurrent vitamin supplementation with oral folic acid and intramuscular vitamin B12.

1. Bladder Cancer, Primary Carcinoma of the Urethra, Upper GU Tract Tumors, or Urothelial Carcinoma of the Prostate

- Authorization of 3 months may be granted for members who are prescribed Alimta for use as single-agent, subsequent therapy for metastatic disease.

2. Malignant Pleural Mesothelioma (MPM)

Authorization of 3 months may be granted for members who are prescribed Alimta for ANY of the following:

- a. Clinical Stage I-III disease and epithelial or mixed histology, for use as one of the following:
 - I. Induction chemotherapy for medically operable disease, in combination with cisplatin
 - II. Treatment of unresectable or medically inoperable (i.e., patient is not a candidate for surgery) disease as
 - a) a single agent
 - b) in combination with cisplatin or carboplatin
 - c) in combination with Avastin (bevacizumab) and cisplatin
 - III. Treatment of resected disease in members who were not treated with induction chemotherapy, as a single agent or in combination with cisplatin or carboplatin
- b. Treatment of Clinical Stage IV disease or sarcomatoid or mixed histology tumors
 - I. as a single agent
 - II. in combination with cisplatin or carboplatin
 - III. in combination with Avastin (bevacizumab) and cisplatin
- c. Subsequent chemotherapy as a single agent

3. Non-Small Cell Lung Cancer (Non-Squamous)**3.1 Neoadjuvant or Adjuvant Therapy (Stage I-III)**

Authorization of 3 months may be granted for members who are prescribed Alimta for use as ANY of the following:

- a. Preoperative concurrent chemoradiation in combination with cisplatin or carboplatin
- b. Neoadjuvant or induction chemotherapy in combination with cisplatin
- c. Initial treatment as definitive concurrent chemoradiation in combination with cisplatin, or carboplatin

- d. Adjuvant chemotherapy in combination with cisplatin
- e. Adjuvant concurrent chemoradiation in combination with cisplatin or carboplatin
- f. Concurrent chemoradiation in combination with cisplatin or carboplatin for locoregional recurrence

3.2 Chemotherapy for Recurrent or Metastatic (Stage IV) Disease

Authorization of 3 months may be granted for members who are prescribed Alimta for recurrent or metastatic (Stage IV) disease and ANY of the following criteria are met:

- a. First-line treatment in combination with cisplatin, carboplatin, or carboplatin and pembrolizumab in members with Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) 0-2
- b. First-line treatment as single agent in members with ECOG PS 0-2
- c. First-line treatment in cisplatin- or carboplatin-based regimens in combination with bevacizumab for members with ECOG PS 0-1 and no history of recent hemoptysis
- d. Continuation maintenance therapy as a single agent or in combination with bevacizumab in members who achieved tumor response or stable disease following first-line chemotherapy (if Alimta or Alimta and bevacizumab were used as first-line treatment above)
- e. Subsequent therapy as a single agent, or in combination with cisplatin, carboplatin, or carboplatin and pembrolizumab for members with ECOG PS 0-2 who meet any of the following criteria:
 - I. Tumor is EGFR positive and the member has progressed on Tarceva (erlotinib), Gilotrif (afatinib), Iressa (gefitinib), or Tagrisso (osimertinib)
 - II. Tumor is BRAF V600E positive
 - III. Tumor is ALK positive and the member has progressed on Xalkori (crizotinib), Zykadia (ceritinib), Alecensa (alectinib), or Alunbrig (brigatinib)
 - IV. Tumor is ROS1 positive and the member has progressed on Xalkori (crizotinib)
 - V. Tumor is PD-L1 positive and EGFR, ALK, ROS1, and BRAF negative/unknown
- f. Subsequent therapy as a single agent for members with ECOG PS 0-2 if disease progressed after treatment with a first-line cytotoxic regimen and member did not previously receive Alimta
- g. Subsequent therapy in combination with cisplatin- or carboplatin-based regimens in combination with Avastin (bevacizumab) for members with ECOG PS 0-1 and no history of hemoptysis who meet all of the following criteria:
 - I. Tumor is EGFR positive and the member has progressed on Tarceva (erlotinib), Gilotrif (afatinib), Iressa (gefitinib), or Tagrisso (osimertinib)
 - II. Tumor is BRAF V600E positive
 - III. Tumor is ALK positive and the member has progressed on Xalkori (crizotinib), Zykadia (ceritinib), Alecensa (alectinib), or Alunbrig (brigatinib)
 - IV. Tumor is ROS1 positive and the member has progressed on Xalkori (crizotinib)
 - V. Tumor is PD-L1 positive and EGFR, ALK, ROS1, BRAF negative/unknown, and the member has progressed on Keytruda (pembrolizumab)

4. Ovarian Cancer (Epithelial)/Fallopian Tube Cancer/Primary Peritoneal Cancer

Authorization of 3 months may be granted for members who are prescribed Alimta as single-agent therapy for persistent disease or recurrence

5. Primary CNS Lymphoma

Authorization of 3 months may be granted for members with progressive or recurrent disease when any of the following criteria are met:

- a. Member has previously received whole brain radiation therapy and Alimta will be used as a single agent, OR
- b. Member has previously received methotrexate-based chemotherapy without radiation therapy and Alimta will be used as a single agent or in combination with radiation therapy, OR
- c. Member has previously received high-dose chemotherapy with stem cell rescue and Alimta will be used as a single agent

6. Thymoma and Thymic Carcinoma

Authorization of 3 months may be granted for members prescribed Alimta as a single-agent, second-line therapy

F. CONTINUATION OF THERAPY

1. No previous authorization/precertification:

All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section E.

2. Reauthorization:

Members who were previously approved for Alimta by HMSA/ CVS may request reauthorizations after their initial approval. Approval for an additional 3 months may be granted if the following information is supplied:

- A current oncology note documenting the patient's response to treatment showing no progression of disease
- Current imaging studies and other objective measures showing no progression of disease when compared with previous results

G. DOSING AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

H. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the [HMSA medical policy web site](#) for the fax form.

I. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4),

generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

REFERENCES

1. Alimta [package insert]. Indianapolis, IN: Eli Lilly and Company USA, LLC; February 2015.
2. The NCCN Drugs & Biologics Compendium™. © 2017 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed August 9, 2017.

Document History

09/01/2007	Original effective date
11/01/2014	Revision effective date
05/2016	Annual review
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