

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Alimta (pemetrexed disodium)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Alimta (pemetrexed disodium)

### APPROVAL CRITERIA

Requests for Alimta (pemetrexed disodium) may be approved if the following criteria are met:

- I. Individual has a diagnosis of malignant mesothelioma; **AND**
  - A. Individual is using in combination with cisplatin or carboplatin (Label, NCCN 2A); **OR**
  - B. Individual is using as a first-line of therapy in combination with cisplatin or carboplatin **AND** bevacizumab (or bevacizumab biosimilar) (Label, NCCN 2A); **AND**
    1. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
    2. Individual does not have a history of hemoptysis or thrombosis; **AND**
    3. Disease presentation is unresectable; **OR**
  - C. Individual is using as single agent for subsequent therapy (NCCN 1); **AND**
    1. Alimta (pemetrexed) was not administered as first-line; **OR**
    2. Alimta (pemetrexed) was used as first-line with good sustained response;

**OR**

- II. Individual has a diagnosis of locally advanced or metastatic non-squamous, non-small cell lung cancer (NSCLC); **AND**
  - A. Individual is using as a single agent after prior chemotherapy; **OR**
  - B. Individual is using as a first-line of therapy in combination with platinum-based chemotherapy with or without bevacizumab (or bevacizumab biosimilar) (NCCN 2A); **OR**
  - C. Individual is using as second-line therapy (first-line chemotherapy) in combination with platinum-based chemotherapy with or without bevacizumab (or bevacizumab biosimilar) if tyrosine-kinase inhibitor (TKI)/anaplastic lymphoma kinase (ALK) targeted agent was given as first-line therapy (NCCN 1); **OR**
  - D. Individual is using for maintenance therapy when disease has not progressed following four cycles of platinum-based, first-line therapy; **OR**

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E. Individual is using in combination with pembrolizumab (Keytruda) and platinum chemotherapy for initial treatment in those with confirmation of EGFR, ALK, ROS1, and BRAF mutations that are negative or unknown aberrations (Label, NCCN 2A);

**OR**

F. Individual is using as continuous maintenance therapy until disease progression, if given first-line as part of Keytruda (pembrolizumab)/platinum chemotherapy/and pemetrexed regimen (NCCN 1);

**OR**

III. Individual is using as a single-agent therapy; **AND**

IV. Individual has one of the following (NCCN 2A):

A. Individual has a diagnosis for persistent or recurrent ovarian cancer; **OR**

B. Individual has a diagnosis for thymic cancer and thymomas and using as second-line therapy.

Requests for Alimta (pemetrexed disodium) may **not** be approved for the:

I. Individual has a diagnosis of squamous cell non-small cell lung cancer; **OR**

II. When the above criteria are not met and for all other indications.

#### Key References:

1. Barlesi F, Scherpereel A, Rittmeyer A, et al. Randomized phase III trial of maintenance bevacizumab with or without pemetrexed after first-line induction with bevacizumab, cisplatin, and pemetrexed in advanced nonsquamous non-small-cell lung cancer: AVAPERL (MO22089). *J Clin Oncol*. 2013; 31(24):3004-3011
2. Carteri G, Manegold C, Garcia GM, et al. Malignant peritoneal mesothelioma-Results from the International Expanded Access Program using pemetrexed alone or in combination with a platinum agent. *Lung Cancer*. 2009; 64(2):211-218.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 23, 2019.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
7. Jänne PA, Wozniak AJ, Belani CP, et al. Open-label study of pemetrexed alone or in combination with cisplatin for the treatment of patients with peritoneal mesothelioma: outcomes of an expanded access program. *Clin Lung Cancer*. 2005; 7(1):40-46.
8. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on December 23, 2019.
  - a. Central Nervous System Cancers. V3.2019. Revised October 18, 2019.
  - b. Malignant Pleural Mesothelioma. V1.2020. Revised November 27, 2019.
  - c. Non-Small Cell Lung Cancer. V2.2020. Revised December 23, 2019.
  - d. Ovarian Cancer, including fallopian tube cancer and primary peritoneal cancer. V3.2019. Revised November 26, 2019.
  - e. Thymomas and Thymic Carcinomas. V1.2020. Revised November 27, 2019.
9. Patel JD, Socinski MA, Garon EB, et al. PointBreak: a randomized phase III study of pemetrexed plus carboplatin and bevacizumab followed by maintenance pemetrexed and bevacizumab versus paclitaxel plus carboplatin and bevacizumab

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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followed by maintenance bevacizumab in patients with stage IIIB or IV nonsquamous non-small-cell lung cancer. J Clin Oncol. 2013; 31(34):4349-4357

10. Raizer JJ, Rademaker A, Evens AM, et al. Pemetrexed in the treatment of relapsed/refractory primary central nervous system lymphoma. Cancer. 2012; 118(15):3743-3748.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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