

**Clinical Policy: Pemetrexed (Alimta)**

Reference Number: CP.PHAR.368

Effective Date: 10.31.17

Last Review Date: 02.19

Line of Business: HIM-Medical Benefit, Medicaid

[Coding Implications](#)  
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Pemetrexed (Alimta<sup>®</sup>) is an antifolate antineoplastic agent.

**FDA Approved Indication(s)**

Alimta is indicated for:

- Treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC)
  - in combination with cisplatin as initial treatment;
  - in combination with carboplatin and pembrolizumab as initial treatment;
  - as a single agent as maintenance treatment for disease that has not progressed after four cycles of platinum-based first-line chemotherapy;
  - as a single agent after prior chemotherapy;
- Initial treatment of malignant pleural mesothelioma, in combination with cisplatin, for patients whose disease is unresectable or who are otherwise not candidates for curative surgery.

Limitation(s) of use: Alimta is not indicated for the treatment of patients with squamous cell non-small cell lung cancer.

**Policy/Criteria**

*Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Alimta is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria****A. Non-Small Cell Lung Cancer or Mesothelioma** (must meet all):

1. One of the following diagnoses (a or b):
  - a. Nonsquamous NSCLC;
  - b. Malignant pleural mesothelioma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Request meets one of the following (a or b):
  - a. Dose does not exceed 500mg per m<sup>2</sup> administered every 21 days;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**B. Thymoma or Thymic Carcinoma (off-label) (must meet all):**

1. Diagnosis of thymoma or thymic carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Prescribed as second line therapy (*initial treatment may include surgery, radiation therapy, chemotherapy*);
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**C. Ovarian/Fallopian Tube/Primary Peritoneal Cancer (off-label) (must meet all):**

1. Diagnosis of ovarian, fallopian tube, or primary peritoneal cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Disease is persistent or recurrent;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**D. Primary Central Nervous System Lymphoma (off-label) (must meet all):**

1. Diagnosis of relapsed or refractory central nervous system lymphoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**E. Urothelial Carcinoma (off-label) (must meet all):**

1. Diagnosis of urothelial carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Prescribed as subsequent systemic therapy;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

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**F. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

**II. Continued Therapy**

**A. All Indications in Section I (must meet all):**

1. Currently receiving medication via Centene benefit or documentation supports that member has received Alimta for any of the covered indications and has had at least one dose in the last 90 days;
2. If request is for a dose increase, request meets one of the following (a or b):
  - a. New dose does not exceed 500mg/m<sup>2</sup> administered every 21 days;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 6 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid and HIM-Medical Benefit.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

NSCLC: non-small cell lung cancer

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

None reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
NSCLC	500 mg/m <sup>2</sup> IV on Day 1 of each 21-day cycle as a single agent or in combination with cisplatin, or carboplatin and pembrolizumab.	500 mg/m <sup>2</sup> IV infusion every 21 days

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Indication	Dosing Regimen	Maximum Dose
Malignant pleural mesothelioma	500 mg/m <sup>2</sup> IV on Day 1 of each 21-day cycle in combination with cisplatin.	

#### VI. Product Availability

Vial for injection: 100 mg, 500 mg

#### VII. References

1. Alimta Prescribing Information. Indianapolis, IN: Eli Lilly Pharmaceuticals; June 2018. Available at: [www.alimta.com](http://www.alimta.com). Accessed October 8, 2018.
2. Non-small cell lung cancer (Version 6.2018). National Comprehensive Cancer Network Guidelines. Available at [www.nccn.org](http://www.nccn.org). Accessed October 08, 2018.
3. Malignant pleural mesothelioma (Version 2.2018). National Comprehensive Cancer Network Guidelines. Available at [www.nccn.org](http://www.nccn.org). Accessed October 8, 2018
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed October 8, 2018.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed October 8, 2018.

#### Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9305	Injection, pemetrexed, 10 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	10.31.17	02.18
1Q 2019 annual review; HIM-Medical Benefit line of business added; age added; new NSCLC labeled indication added to indication section; bladder cancer relabeled as UC, methotrexate trial removed from CNS lymphoma and FDA approved treatments removed from ovarian cancer to encompass NCCN uses; references reviewed and updated.	11.13.18	02.19

#### Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional

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organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence.

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Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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