RXADVANCE
2 Park Central Drive
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Clinical Policy Title:	pemetrexed
Policy Number:	RxA.350
Drug(s) Applied:	Alimta®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Pemetrexed (Alimta®) is an antifolate antineoplastic agent.

Alimta® is indicated for:

- Treatment of locally advanced or metastatic non squamous non-small cell lung cancer (NSCLC):
  - In combination with cisplatin as initial treatment;
  - In combination with platinum therapy and pembrolizumab as initial treatment of patients with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations;
  - 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Pemetrexed (Alimta®)	NSCLC	500 mg/m^2 IV on Day 1 of each 21-day cycle as a single agent or in combination with cisplatin, or platinum therapy and pembrolizumab	500 mg/m^2 IV infusion every 21 days
	Malignant pleural mesothelioma	500 mg/m^2 IV on Day 1 of each 21-day cycle in combination with cisplatin	500 mg/m^2 IV infusion every 21 days

Dosage Forms

- Single-dose vial for injection: 100 mg, 500 mg

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of one of the following (a or b):
   a. Non-squamous NSCLC;
   b. Malignant pleural mesothelioma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):*
   a. Dose does not exceed 500 mg per m^2 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*).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months
HIM: 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 ≥ 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*).*
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months
HIM: 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 ≥ 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*).*
   * Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months
HIM: 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 or hematologist;
3. Age ≥ 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*). *

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months
HIM: 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 ≥ 18 years of age or older;
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*).*

* Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months
HIM: 6 months

II. Continued Therapy

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met the initial approval criteria for a covered indication and has had at least one dose in the last 90 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 500 mg/m^2 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*).

* Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 12 months
Medicaid: 6 months
HIM: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
ALK: anaplastic lymphoma kinase
EGFR: epidermal growth factor receptor
NSCLC: non-small cell lung cancer
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - history of severe hypersensitivity reaction to pemetrexed.

- Boxed warning(s):
  - None.

References

1. Alimta Prescribing Information. Indianapolis, IN: Eli Lilly Pharmaceuticals; January 2019. Available at: www.alimta.com. Accessed July 28, 2020.
2. Non-small cell lung cancer (Version 1.2020). National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed July 28, 2020.
3. Malignant pleural mesothelioma (Version 2.2019). National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed July 28, 2020.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 28, 2020.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed July 28, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1) Policy title was updated. 2) Indications were updated. 3) Initial Approval criteria updated. 4) Continued Therapy Approval criteria II.A.1 was rephrased. 5) Appendices updated. 6) References were updated.	07/28/2020	09/14/2020