Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2020**
Policy Number: PA.CP.PHAR.368	**Effective Date: 01/01/2018** **Revision Date: 01/15/2020**
Policy Name: Pemetrexed (Alimta)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2020 annual review; added updated FDA indication: NSCLC without EGFR or ALK gene mutation in combination with platinum chemotherapy and pembrolizumab; this is already a covered use, therefore no modification to criteria was required; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Pemetrexed (Alimta)

Reference Number: PA.CP.PHAR.368
Effective Date: 10.31.17
Last Review Date: 01.20

Coding Implications
Revision Log

Description
Pemetrexed (Alimta®) 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 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.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with PA Health & Wellness 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 ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 500mg/m^2 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. Thymomas or Thymic Carcinomas (off-label) (must meet all)**:**
1. Diagnosis of thymomas or thymic carcinomas;
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*).

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 ≥ 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 primary central nervous system lymphoma;
2. Prescribed by or in consultation with an oncologist;
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*).

Approval duration: 6 months

E. Urothelial Carcinoa (off-label) (must meet all)**:**
1. Diagnosis of urothelial carinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 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

F. Cervical Cancer (off-label) (must meet all)**:**
1. Diagnosis of Cervical Cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years
4. Prescribed as second-line therapy as a single agent for one of the following (a or b)

a. Local/regional recurrence
b. Stage IVB or distant metastases

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

G. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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 500mg/m^2 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 PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;

   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase
EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
NSCLC: non-small cell lung cancer

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

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

- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	500 mg/m^2 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^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.	

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. Accessed November 13, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 13, 2019.
3. Non-small cell lung cancer (Version 6.2018). National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed November 13, 2019.
4. Malignant pleural mesothelioma (Version 2.2018). National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed November 13, 2019

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
1Q 2019 annual review; 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.	01/19	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2020 annual review; added updated FDA indication: NSCLC without EGFR or ALK gene mutation in combination with platinum chemotherapy and pembrolizumab; this is already a covered use, therefore no modification to criteria was required; references reviewed and updated.	01/2020	