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: 02/01/2022**
Policy Number: PA.CP.PHAR.368	**Effective Date: 01/01/2018** **Revision Date: 01/2022**
Policy Name: Pemetrexed (Alimta, Pemfexy)	

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 2022 annual review: added other sources of malignant mesotheliomas per NCCN; added criterion for use as single-agent therapy for thymomas/thymic carcinomas, ovarian/fallopian tube/primary peritoneal cancers, and primary central nervous system lymphomas per NCCN; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Pemetrexed (Alimta, Pemfexy)

Reference Number: PA.CP.PHAR.368
Effective Date: 10.2017
Last Review Date: 01.2022

Coding Implications
Revision Log

Description
Pemetrexed (Alimta®, Pemfexy™) is an antifolate antineoplastic agent.

FDA Approved Indication(s)
Alimta is indicated for:
- In combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations.

Alimta and Pemfexy are indicated:
- In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC).
- As a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
- As a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy.
  Limitations of Use: Alimta and Pemfexy are not indicated for the treatment of patients with squamous cell, non-small cell lung cancer.
- Initial treatment, in combination with cisplatin, of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

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 and Pemfexy 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. One of the following malignant mesotheliomas (i, ii, iii, or iv):
      i. Pleural;
      ii. Peritoneal (off-label);
      iii. Pericardial (off-label);
      iv. Tunica vaginalis testis (off-label);
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. Prescribed as a single agent;
6. 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. Prescribed as a single agent;
6. 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 primary central nervous system lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent for one of the following (a or b):
   a. Relapsed or refractory disease;
   b. Induction therapy if member is unsuitable for or intolerant to high-dose methotrexate;
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

E. 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
   c. Persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC)
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. 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
NCCN: National Comprehensive Cancer Network
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

Single-dose vial for injection: 100 mg (Alimta), 500 mg (Alimta, Pemfexy)

VII. References

1. Alimta Prescribing Information. Indianapolis, IN: Eli Lilly Pharmaceuticals; January 2019. Available at: www.alimta.com. Accessed November 13, 2021.
2. Pemfexy Prescribing Information. Woodcliff Lake, NJ: Eagle Pharmaceuticals, Inc. February 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209472s000lbl.pdf. Accessed November 13, 2021.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 13, 2021.
4. Non-Small Cell Lung Cancer Version 7.2021. National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed November 13, 2021.
5. Malignant Pleural Mesothelioma Version 2.2021. National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed November 13, 2021.
6. Thymomas and Thymic Carcinomas Version 1.2021. National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed November 13, 2021.

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	
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	
1Q 2021 annual review: induction therapy offered for primary CNS lymphoma per NCCN; urothelial carcinoma off-label use removed per NCCN; references reviewed and updated.	01/2021	
1Q 2022 annual review: added other sources of malignant mesotheliomas per NCCN; added criterion for use as single-agent therapy for thymomas/thymic carcinomas, ovarian/fallopian tube/primary peritoneal cancers, and primary central nervous system lymphomas per NCCN; references reviewed and updated.	01/2022	