Clinical Policy Title:	pemetrexed
Policy Number:	RxA.350
Drug(s) Applied:	Alimta®, Pemfexy™
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

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

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 a single agent;
5. Member meets any one of the followings (a or b)
   a. Prescribed as first line therapy or postoperative treatment in patients who are unable to tolerate first-line combination regimens;
   b. Prescribed as second-line therapy for unresectable or metastatic disease
6. 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

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 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

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. 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 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

E. Cervical Cancer (off-label) (must meet all):
1. Diagnosis of Cervical Cancer;
2. Prescribed by or in consultation with an oncologist or gynecologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent for second line or subsequent therapy for one of the following (a or b):
   a. local/regional recurrence;
   b. stage IVB or distant metastases;
5. 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

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 the member has met 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

References

1. National Comprehensive Cancer Network Guidelines. Non-small cell lung cancer. Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed January 20, 2023.
2. National Comprehensive Cancer Network Guidelines. Thymoma or Thymic Carcinoma. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf. Accessed January 20, 2023.
3. National Comprehensive Cancer Network Guidelines. Malignant pleural mesothelioma. Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/meso_pleural.pdf. Accessed January 20, 2023.
4. National Comprehensive Cancer Network Guidelines. Ovarian/Fallopian Tube/Primary Peritoneal Cancer. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed January 20, 2023.
5. National Comprehensive Cancer Network Guidelines. Primary Central Nervous System Lymphoma. Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed January 20, 2023.
6. National Comprehensive Cancer Network Guidelines. Cervical Cancer. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed January 20, 2023.

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) References were updated.	07/28/2020	09/14/2020
Policy was reviewed: 1) Initial Approval Criteria and Continued Therapy Criteria approval duration was updated to remove HIM approval duration. 2) References were reviewed and updated.	06/01/2021	09/14/2021
Policy was reviewed: 1. Clinical Policy Title, Drug(s) Applied: Updated to include new drug Pemfexy™. 2. Initial Approval Criteria, 1.D.4.a and 1.D.4.b: Updated to include new diagnostic criteria Pemetrexed is prescribed for one of the following (a or b): Relapsed or refractory disease; Induction therapy as a single agent if	03/11/2022	4/18/2022

member is unsuitable for or intolerant to high-dose methotrexate. 3. Initial Approval Criteria (I.D): Updated to be removed. 4. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.B.5 : Updated prescribing regimen criteria from Prescribed as second-line therapy (initial treatment may include surgery, radiation therapy, chemotherapy); to Member meets any one of the followings (a or b) a. Prescribed as first line therapy or postoperative treatment in patients who are unable to tolerate first-line combination regimens; b. Prescribed as second-line therapy for unresectable or metastatic disease. 2. Initial Approval Criteria. I.C.5: Updated to add prescribed as a single agent. 3. Initial Approval Criteria, I.E: Updated to include new off label Indication. 4. References were reviewed and updated.	01/20/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023