Pemetrexed:
Alimta®; Pemfexy™
(Intravenous)

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I. Length of Authorization [15]

Coverage will be provided for six months and may be renewed unless otherwise specified.

- Thymomas/Thymic Carcinoma: Coverage will be provided for six 21-day cycles and may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Alimta 100 mg powder for injection: 4 vials every 21 days
- Alimta 500 mg powder for injection: 4 vials every 21 days
- Pemfexy 500 mg solution for injection: 4 vials every 21 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- CNS Lymphoma and Ovarian Cancer: 230 billable units every 21 days
- All other indications: 130 billable units every 21 days

III. Initial Approval Criteria [1,2]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Primary Central Nervous System (CNS) Lymphoma ‡ [3,16,26]

- Used as a single agent as induction therapy in patients unsuitable for or intolerant to high-dose methotrexate (MTX); **OR**
- Used as single agent therapy for relapsed or refractory disease; **AND**
  - Patient received prior whole brain radiation therapy (RT); **OR**

- Patient received a prior high-dose MTX-based regimen without prior radiation therapy; **OR**
- Used in combination with whole brain RT or involved field RT in patients who received a prior high-dose MTX-based regimen without prior RT with either no response or short response (<12 month duration) to prior regimen; **OR**
- Patient received prior high-dose chemotherapy with stem cell rescue

Malignant Pleural* Mesothelioma † Φ [3,4,5,6,10,26]

- Used in combination with cisplatin or carboplatin; **AND**
  - Used as initial therapy; **OR**
  - Patient has stage I-IIIA disease with epithelioid or biphasic histology; **AND**
    - Used as induction therapy; **OR**
    - Patient has resected disease not treated with induction chemotherapy; **OR**
- Used as a single agent; **AND**
  - Used as initial therapy; **OR**
  - Used as subsequent therapy, if not administered first-line; **OR**
  - Used as a re-challenge, if pemetrexed was administered first-line with a good sustained response at the time initial chemotherapy was interrupted; **OR**
  - Used for resected stage I-IIIA disease with epithelioid or biphasic histology not treated with induction chemotherapy; **OR**
- Used in combination with bevacizumab and either cisplatin or carboplatin as initial therapy for unresectable disease

**peritoneal, pericardial, and tunica vaginalis testis mesothelioma will be evaluated on a case-by-case basis*

Non-Squamous Non-Small Cell Lung Cancer (NSNSCLC) † [3,7,8,9,11,12,28]

- Used in combination with carboplatin or cisplatin; **AND**
  - Used as induction, neoadjuvant, or adjuvant therapy; **OR**
  - Used as concurrent chemoradiation for locoregional recurrence or symptomatic local disease in the mediastinal lymph nodes or for superior vena cava obstruction; **OR**
  - Used as initial therapy as definitive concurrent chemoradiation for unresectable, advanced, or metastatic disease; **OR**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used for PD-L1 ≥1% tumors that are EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET rearrangement negative*****; **AND**
      - Used in combination with pembrolizumab and either carboplatin or cisplatin in patients with PS 0-2; **OR**
      - Used in combination with nivolumab, ipilimumab, and either carboplatin or cisplatin in patients with PS 0-2; **OR**

- Used for one of the following:
  - PD-L1 <1% and EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET rearrangement negative* tumors
  - BRAF V600E-mutation, NTRK gene fusion, MET exon-14 skipping mutation, or RET rearrangement positive tumors; **AND**
    - Used as a single agent in patients with PS 2; **OR**
    - Used in combination with pembrolizumab and either carboplatin or cisplatin in patients with PS 0-1; **OR**
    - Used in combination with cisplatin in patients with PS 0-1; **OR**
    - Used in combination with carboplatin in patients with PS 0-2; **OR**
    - Used in combination with nivolumab, ipilimumab, and either carboplatin or cisplatin in patients with PS 0-1; **OR**
    - Used in combination with bevacizumab and either cisplatin or carboplatin in patients with PS 0-1; **OR**

- Used as subsequent therapy; **AND**
  - Used as a single-agent (if not previously given) in patients with a PS 0-2; **OR**
  - Used for one of the following:
    - EGFR, ALK, or ROS1 positive tumors who received prior targeted therapy§ for those aberrations
    - BRAF V600E-mutation, NTRK gene fusion, MET exon-14 skipping mutation, or RET rearrangement positive tumors
    - PD-L1 ≥ 1% tumors that are EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET rearrangement negative* with prior PD-1/PD-L1 inhibitor therapy but no prior platinum doublet chemotherapy; **AND**
      - Used in combination with pembrolizumab and either carboplatin or cisplatin in patients with PS 0-1 *(excluding use in patients who have received prior PD-1/PD-L1 inhibitor therapy)*; **OR**
      - Used in combination with cisplatin in patients with PS 0-1; **OR**
      - Used in combination with carboplatin in patients with PS 0-2; **OR**
      - Used in combination with nivolumab, ipilimumab, and either carboplatin or cisplatin in patients with PS 0-1 *(excluding use in patients who have received prior PD-1/PD-L1 inhibitor therapy)*; **OR**
      - Used in combination with bevacizumab and either cisplatin or carboplatin in patients with PS 0-1; **OR**

- Used as maintenance therapy in patients who have achieved tumor response or stable disease following initial therapy; **AND**
  - Used as a single agent for continuation maintenance therapy; **OR**
  - Used as a single agent for switch maintenance therapy; **OR**
  - Used for continuation maintenance therapy in combination with bevacizumab following a first-line bevacizumab/pemetrexed/platinum chemotherapy regimen; **OR**

- Used for continuation maintenance therapy in combination with pembrolizumab following a first-line pembrolizumab/pemetrexed and either carboplatin or cisplatin regimen

** Note: If there is insufficient tissue to allow testing for all of the EGFR, ALK, ROS1, BRAF, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

Thymomas/Thymic Carcinoma ‡ [3,14,15,25]

- Used for second-line treatment of unresectable or metastatic disease; **AND**
- Used as a single agent

Ovarian Cancer (epithelial ovarian/fallopian tube/primary peritoneal cancer) ‡ [3,13,24]

- Used for disease progression, stable or persistent disease (if not on maintenance therapy), or disease relapse; **AND**
- Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 and no radiographic evidence of disease); **AND**
- Used as a single agent

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*) §
Sensitizing *EGFR* mutation-positive tumors – Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib
ALK rearrangement-positive tumors – Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib
ROS1 rearrangement-positive tumors – Ceritinib – Crizotinib – Entrectinib
BRAF V600E-mutation positive tumors – Dabrafenib ± Trametinib – Vemurafenib
NTRK Gene Fusion positive tumors – Larotrectinib – Entrectinib
PD-1/PD-L1 expression-positive tumors (≥1%) – Pembrolizumab – Atezolizumab – Nivolumab ± ipilimumab
MET Exon-14 skipping mutations – Capmatinib – Crizotinib

RET rearrangement-positive tumors – Selpercatinib – Cabozantinib – Vandetanib

IV. Renewal Criteria [1,2]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: bone marrow suppression (e.g., neutropenia, febrile neutropenia, thrombocytopenia, anemia), renal impairment (CrCl < 45 mL/min), bullous and exfoliative skin toxicity (e.g., Stevens-Johnson Syndrome/Toxic epidermal necrolysis), interstitial pneumonitis, radiation recall, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

Continuation of Maintenance Therapy for Non-Squamous Non-Small Cell Lung Cancer (NSCLC)

- *Refer to Section III for criteria*

Thymomas/Thymic Carcinoma

- May not be renewed

V. Dosage/Administration [1,2,13,15,16]

Indication	Dose
Non-Squamous NSCLC, Malignant Pleural Mesothelioma	Administer 500 mg/m^2 intravenously every 21 days, until disease progression or unacceptable toxicity
Primary CNS Lymphoma, Ovarian Cancer	Administer 900 mg/m^2 intravenously every 21 days, until disease progression or unacceptable toxicity
Thymomas/Thymic Carcinoma	Administer 500 mg/m^2 intravenously every 21 days for a maximum of 6 cycles in absence of disease progression or unacceptable toxicity
• Supplement with oral folic acid and intramuscular vitamin B_{12} • Avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration in patients with CrCl <80 mL/min. • Do not dose in patients with CrCl <45 mL/min	

VI. Billing Code/Availability Information

HCPCS Code:

- J9305 – Injection, pemetrexed, not otherwise specified, 10 mg; 1 billable unit = 10mg
- J9304 – Injection, pemetrexed (pemfexy), 10 mg; 1 billable unit = 10mg *(Effective 10/1/20)*

NDC:

- Alimta 100 mg powder for injection; single-use vial: 00002-7640-xx
- Alimta 500 mg powder for injection; single-use vial: 00002-7623-xx
- Pemfexy 500 mg/20 mL solution for injection, single-use vial: 42367-0531-xx

VII. References

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2. Pemfexy [package insert]. Woodcliff Lake, NJ; Eagle Pharmaceuticals, Inc; February 2020. Accessed July 2020.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for pemetrexed. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2020.
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26. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Malignant Pleural Mesothelioma Version 1.2020. National Comprehensive Cancer Network, 2020. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2020.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung

ICD-10	ICD-10 Description
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C37	Malignant neoplasm of thymus
C38.4	Malignant neoplasm of pleura
C45.0	Mesothelioma of pleura
C45.1	Mesothelioma of peritoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C83.30	Diffuse large B-cell lymphoma unspecified site

ICD-10	ICD-10 Description
C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites
C83.80	Other non-follicular lymphoma, unspecified site
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
D15.0	Benign neoplasm of thymus
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.43	Personal history of malignant neoplasm of ovary

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT,	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC