Pemetrexed:
Alimta®; Pemfexy™; Pemetrexed™
(Intravenous)

Document Number: IC-0007

Last Review Date: 12/01/2022
Date of Origin: 07/20/2010
Dates Reviewed: 09/2010, 12/2010, 03/2011, 06/2011,0 9/2011, 12/2011, 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 05/2018, 09/2018, 12/2018, 03/2019, 06/2019, 09/2019, 12/2019, 03/2020, 06/2020, 09/2020, 12/2020, 03/2021, 06/2021, 09/2021, 12/2021, 03/2022, 06/2022, 09/2022, 12/2022

I. Length of Authorization [15,26,28-30]

Coverage will be provided for 6 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.
- MPeM and MPM: Coverage will be provided for six 21-day cycles and may not be renewed when used in combination with platinum therapy and bevacizumab.

II. Dosing Limits

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

- Alimta 100 mg powder for injection in a single-use vial: 4 vials every 21 days
- Alimta 500 mg powder for injection in a single-use vial: 4 vials every 21 days
- Pemfexy 500 mg solution for injection in a multi-dose vial: 4 vials every 21 days
- Pemetrexed disodium 750mg powder for injection: 2 vials every 21 days
- Pemetrexed disodium 1000mg powder for injection: 2 vials every 21 days
- Pemetrexed disodium 100mg/4 mL solution for injection: 4 vials every 21 days
- Pemetrexed disodium 500mg/20 mL solution for injection: 4 vials every 21 days
- Pemetrexed disodium 1000mg/40 mL solution for injection: 2 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

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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 ‡ [3,16,27]

- Used as single-agent; **AND**
  - Used as induction therapy in patients unsuitable for or intolerant to high-dose methotrexate (MTX); **OR**
  - Used for relapsed or refractory disease

Malignant Peritoneal* Mesothelioma (MPeM) ‡ [3,29]

- Used as first-line therapy; **AND**
  - Used in combination with bevacizumab and cisplatin followed by single-agent maintenance bevacizumab (preferred) as first-line systemic therapy for unresectable disease; **OR**
  - Used as a single agent OR in combination with cisplatin or carboplatin (if cisplatin ineligible) for diffuse or recurrent disease; **OR**
- Used as subsequent therapy; **AND**
  - Used in combination with cisplatin or carboplatin (if cisplatin ineligible), with or without bevacizumab, if immunotherapy was administered as first-line treatment; **OR**
  - Used as a single agent; **AND**
    - Pemetrexed was not administered first-line; **OR**
    - Used as rechallenge if pemetrexed was administered first-line with a good sustained response at the time initial chemotherapy was interrupted

Malignant Pleural* Mesothelioma (MPM) † Φ [1-6,10,26]

- Used as induction therapy; **AND**
  - Used in combination with cisplatin or carboplatin (if cisplatin ineligible) in patients with epithelioid histology; **OR**
- Used as first-line therapy; **AND**
  - Used in combination with bevacizumab and cisplatin followed by single-agent maintenance bevacizumab (preferred) as first-line systemic therapy ; **OR**
  - Used as a single agent OR in combination with cisplatin or carboplatin (if cisplatin ineligible) for resected or recurrent disease; **OR**
- Used as subsequent therapy; **AND**
  - Used in combination with cisplatin or carboplatin (if cisplatin ineligible), with or without bevacizumab, if immunotherapy was administered as first-line treatment; **OR**
  - Used as a single agent; **AND**

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- Pemetrexed was not administered first-line; **OR**
- Used as rechallenge if pemetrexed was administered first-line with a good sustained response at the time initial chemotherapy was interrupted

***** *Note: May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma.*

Non-Squamous Non-Small Cell Lung Cancer (NS-NSCLC) † [1-3,7-9,11,12,28,30]

- Used in combination with carboplatin or cisplatin-containing regimen; **OR**
- Used as single-agent therapy; **AND**
  - Patient has 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 for PD-L1 ≥1% tumors that have negative actionable molecular biomarkers*; **OR**
    - Used as first-line therapy for PD-L1 <1% and tumors that have negative actionable molecular markers * OR BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon-14 skipping mutation, EGFR exon 20 mutation, KRAS G12C mutation, or RET rearrangement positive tumors; **OR**
    - Used as subsequent therapy for first progression after initial systemic therapy; **OR**
    - Used continuation or switch maintenance therapy in patients who have achieved tumor response or stable disease following initial therapy (*Note: Continuation maintenance therapy may also be given in combination with bevacizumab or pembrolizumab*)

***** *Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, RET rearrangement, and ERBB2 (HER2). If there is insufficient tissue to allow testing for all of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2) 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 as a single agent; **AND**
  - Used as first line therapy or postoperative treatment in patients who are unable to tolerate first-line combination regimens; **OR**
  - Used as second-line therapy for unresectable or metastatic disease

Ovarian Cancer (Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer) ‡ [3,13,24]

- Used as single-agent therapy; **AND**
  - Patient has recurrent or persistent disease; **AND**
    - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **OR**
  - Patient has recurrent low-grade serous carcinoma

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† 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	*ALK* rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*NTRK1/2/3* gene fusion positive tumors	*ERBB2 (HER2)* mutation positive tumors
– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab *(exon-20 insertion)* – Mobocertinib *(exon-20 insertion)*	– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib – Lorlatinib	– Dabrafenib ± trametinib – Vemurafenib	– Larotrectinib – Entrectinib	– Fam-trastuzumab deruxtecan-nxki – Ado-trastuzumab emtansine
PD-L1 tumor expression ≥ 1%	PD-L1 tumor expression ≥ 50%	*MET* exon-14 skipping mutations	*RET* rearrangement-positive tumors	*KRAS G12C* mutation positive tumors	
– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab	– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Pralsetinib	– Sotorasib	

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: myelosuppression (e.g., neutropenia, febrile neutropenia, thrombocytopenia, anemia), renal toxicity (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**

MPeM and MPM [26,29]

- May not be renewed when used in combination with platinum therapy and bevacizumab

Thymomas/Thymic Carcinoma [15]

- May not be renewed

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V. Dosage/Administration [1,2,13,15,16,26,28-30]

Indication	Dose
Non-Squamous NSCLC	Administer up to 500 mg/m^2 intravenously every 21 days
MPM, MPeM	Administer 500 mg/m^2 intravenously every 21 days – For 6 cycles only when used in combination with platinum therapy and bevacizumab – All others 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

Product Formulation	Drug	Manufacturer	Type	HCPCS Code	NDC
Pemetrexed Disodium Lyophilisate for inj.	Alimta 100 mg powder for inj. SDV * Alimta 500 mg powder for inj. SDV *	Lilly	Brand	J9305	00002-7640-xx 00002-7623-xx
	Pemetrexed 100 mg powder for inj. Ψ Pemetrexed 500 mg powder for inj. Ψ Pemetrexed 1000 mg powder for inj. Ψ	Hospira	Brand	J9305	00409-1060-xx 00409-1061-xx 00409-1062-xx
	Pemetrexed 750 mg powder for inj.* Pemetrexed 1000 mg powder for inj.*	N/A	Generic	J9305	N/A
Pemetrexed Disodium Solution for injection	Pemetrexed 100mg/4mL inj. SDV Ψ	Sandoz Accord	Brand	J9305	00781-3518-xx 16729-0522-xx
	Pemetrexed 500mg/20mL inj. SDV Ψ	Hospira Sandoz Accord	Brand	J9305	00409-2188-xx 00781-3519-xx 16729-0522-xx
	Pemetrexed 1000mg/40mL inj. SDV Ψ	Hospira Accord	Brand	J9305	00409-3532-xx 16729-0522-xx
Pemetrexed Solution for injection	Pemfexy 500 mg/20 mL inj. MDV	Eagle.	Brand	J9304	42367-0531-xx
	Pemetrexed 100mg/4mL inj. SDV Ψ	Hospira Teva	Brand	J9305 J9314	00409-1045-xx 00480-4516-xx
	Pemetrexed 500mg/20mL inj. SDV Ψ	Teva	Brand	J9314	00480-4514-xx
	Pemetrexed 1000mg/40mL inj. SDV Ψ	Teva	Brand	J9314	00480-4515-xx
Multiple manufacturers produce ANDA generics ***Ψ Approved by the FDA as a 505(b)(2) NDA of the innovator product***					
J9304 – Injection, pemetrexed (pemfexy), 10 mg **J9305 – Injection, pemetrexed, not otherwise specified, 10 mg** **J9314 – Injection, pemetrexed (teva) not therapeutically equivalent to J9305, 10 mg *(Effective 1/1/2023)***					

VII. References

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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

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ICD-10	ICD-10 Description
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
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
C45.0	Mesothelioma of pleura
C45.1	Mesothelioma of peritoneum
C45.2	Mesothelioma of pericardium
C45.7	Mesothelioma of other sites
C45.9	Mesothelioma, unspecified
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
C56.3	Malignant neoplasm of bilateral ovaries
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

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ICD-10	ICD-10 Description
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
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
C85.99	Non-Hodgkin's 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: https://www.cms.gov/medicare-coverage-database/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.

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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