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

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## 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

## 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**

- 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

† 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<br>– Erlotinib<br>– Dacomitinib<br>– Gefitinib<br>– Osimertinib<br>– Amivantamab *(exon-20 insertion)*<br>– Mobocertinib *(exon-20 insertion)* | – Alectinib<br>– Brigatinib<br>– Ceritinib<br>– Crizotinib<br>– Lorlatinib | – Ceritinib<br>– Crizotinib<br>– Entrectinib<br>– Lorlatinib | – Dabrafenib ± trametinib<br>– Vemurafenib | – Larotrectinib<br>– Entrectinib | – Fam-trastuzumab deruxtecan-nxki<br>– 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<br>– Atezolizumab<br>– Nivolumab + ipilimumab | – Pembrolizumab<br>– Atezolizumab<br>– Nivolumab + ipilimumab<br>– Cemiplimab | – Capmatinib<br>– Crizotinib<br>– Tepotinib | – Selpercatinib<br>– Cabozantinib<br>– 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

## 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<br>– For 6 cycles only when used in combination with platinum therapy and bevacizumab<br>– 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 $B_{12}$<br>• Avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration in patients with CrCl <80 mL/min.<br>• 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 * | Lilly | Brand | J9305 | 00002-7640-xx |
| | Alimta 500 mg powder for inj. SDV * | | | | 00002-7623-xx |
| | Pemetrexed 100 mg powder for inj. Ψ | Hospira | Brand | J9305 | 00409-1060-xx |
| | Pemetrexed 500 mg powder for inj. Ψ | | | | 00409-1061-xx |
| | Pemetrexed 1000 mg powder for inj. Ψ | | | | 00409-1062-xx |
| | Pemetrexed 750 mg powder for inj.* | N/A | Generic | J9305 | N/A |
| | Pemetrexed 1000 mg powder for inj.* | | | | |
| Pemetrexed Disodium Solution for injection | Pemetrexed 100mg/4mL inj. SDV Ψ | Sandoz | Brand | J9305 | 00781-3518-xx |
| | | Accord | | | 16729-0522-xx |
| | Pemetrexed 500mg/20mL inj. SDV Ψ | Hospira | Brand | J9305 | 00409-2188-xx |
| | | Sandoz | | | 00781-3519-xx |
| | | Accord | | | 16729-0522-xx |
| | Pemetrexed 1000mg/40mL inj. SDV Ψ | Hospira | Brand | J9305 | 00409-3532-xx |
| | | Accord | | | 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 | Brand | J9305 | 00409-1045-xx |
| | | Teva | | J9314 | 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***<br>***Ψ Approved by the FDA as a 505(b)(2) NDA of the innovator product*** | | | | | |
| **J9304 – Injection, pemetrexed (pemfexy), 10 mg**<br>**J9305 – Injection, pemetrexed, not otherwise specified, 10 mg**<br>**J9314 – Injection, pemetrexed (teva) not therapeutically equivalent to J9305, 10 mg *(Effective 1/1/2023)*** | | | | | |

## VII. References


1. Alimta [package insert]. Indianapolis, IN; Eli Lilly; August 2022. Accessed October 2022.
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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 |

| ICD-10 | ICD-10 Description |
|---|---|
| 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 |
| C57.3 | Malignant neoplasm of parametrium |

| ICD-10 | ICD-10 Description |
|---|---|
| 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. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| 15 | KY, OH | CGS Administrators, LLC |