BILLING AND CODING GUIDE: 
WITH DOSING, DISTRIBUTION, AND CO-PAY INFORMATION

Indication
ALIMTA is indicated in combination with pembrolizumab (pembro) and platinum chemotherapy for the initial treatment of patients with nonsquamous metastatic non-small cell lung cancer (mNSCLC) with no EGFR or ALK genomic tumor aberrations. ALIMTA is indicated for the initial treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) in combination with cisplatin. ALIMTA is indicated for the maintenance treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) whose disease has not progressed after four cycles of platinum-based first-line chemotherapy, as a single agent. ALIMTA is indicated for the treatment of patients with recurrent metastatic nonsquamous non-small cell lung cancer (NSCLC) after prior chemotherapy, as a single agent.

Limitation of Use: ALIMTA is not indicated for the treatment of patients with squamous cell non-small cell lung cancer.
ALIMTA is indicated, in combination with cisplatin, for the initial treatment of patients with malignant pleural mesothelioma (MPM) whose disease is unresectable or who are otherwise not candidates for curative surgery.

Select Important Safety Information
Contraindication
ALIMTA is contraindicated in patients who have a history of severe hypersensitivity reaction to pemetrexed.

ALK=anaplastic lymphoma kinase; EGFR=epidermal growth factor receptor.

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Individual coding decisions should be based upon diagnosis and treatment of individual patients. Eli Lilly and Company does not guarantee success in obtaining insurance payments. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage, coding, and payment policies. Please consult with your legal counsel or reimbursement specialist for any reimbursement or billing questions. For more information, please call the Lilly PatientOne Program at 1-866-472-8663.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Dosing and Administration\(^1\)

Dosing and Administration for ALIMTA When Used in Combination With Cisplatin or Carboplatin and Pembrolizumab (Pembro) for the Treatment of Nonsquamous mNSCLC\(^1\)

<table>
<thead>
<tr>
<th>Indication</th>
<th>ALIMTA</th>
<th>Platinum</th>
<th>Pembro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial treatment for NS mNSCLC with no EGFR or ALK genomic tumor aberrations</td>
<td>500 mg/m(^2) IV over 10 minutes, administered after pembro and prior to platinum chemotherapy, on day 1 of each 21-day cycle for 4 cycles, in patients with a creatinine clearance (calculated by Cockcroft-Gault equation) of 45 mL/min or greater</td>
<td>Refer to the prescribing information for cisplatin or carboplatin</td>
<td>Refer to the prescribing information for pembro</td>
</tr>
</tbody>
</table>

- Following completion of platinum-based therapy, treatment with ALIMTA (with or without pembro) is administered until disease progression or unacceptable toxicity.
- There is no recommended dose for patients whose creatinine clearance is less than 45 mL/min.
- Initiate folic acid 400 mcg to 1000 mcg orally once daily, beginning 7 days before the first dose of ALIMTA and continuing until 21 days after the last dose of ALIMTA.
- Administer vitamin B\(_{12}\) 1 mg intramuscularly, 1 week prior to the first dose of ALIMTA and every 3 cycles thereafter. Do not substitute oral vitamin B\(_{12}\) for intramuscular vitamin B\(_{12}\).
- Administer dexamethasone 4 mg orally twice daily for 3 consecutive days, beginning the day before each ALIMTA administration.
- In patients with creatinine clearances between 45 mL/min and 79 mL/min, avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of ALIMTA. Monitor patients more frequently for myelosuppression, renal, and gastrointestinal toxicity, if concomitant administration of ibuprofen cannot be avoided.

**Dosing modification notes**
- Obtain complete blood count on days 1, 8, and 15 of each cycle. Assess creatinine clearance prior to each cycle. Do not administer ALIMTA if the creatinine clearance is less than 45 mL/min.
- Delay initiation of the next cycle of ALIMTA until recovery of nonhematologic toxicity to grade 0-2, ANC is 1500 cells/mm\(^3\) or higher, and platelet count is 100,000 cells/mm\(^3\) or higher.
- Upon recovery, modify the dosage of ALIMTA in the next cycle as specified in the full Prescribing Information.
- For dosing modifications for cisplatin, carboplatin, and pembro, refer to the respective prescribing information for each medication.

**Select Important Safety Information**

**Warnings and Precautions**

**Myelosuppression and Increased Risk of Myelosuppression Without Vitamin Supplementation:** ALIMTA can cause severe myelosuppression resulting in a requirement for transfusions and which may lead to neutropenic infection. The risk of myelosuppression is increased in patients who do not receive vitamin supplementation. Prior to treatment with ALIMTA, patients must be instructed to initiate supplementation with oral folic acid. Intramuscular injections of vitamin B\(_{12}\) are also required prior to ALIMTA treatment. Folic acid and vitamin B\(_{12}\) supplementation should be continued during treatment and for 21 days after the last dose of ALIMTA as they may reduce the severity of treatment-related hematologic and gastrointestinal toxicities. Obtain a complete blood count at the beginning of each cycle. Do not administer ALIMTA until the ANC is at least 1500 cells/mm\(^3\) and platelet count is at least 100,000 cells/mm\(^3\). Permanently reduce ALIMTA in patients with an ANC of less than 500 cells/mm\(^3\) or platelet count of less than 50,000 cells/mm\(^3\) in previous cycles.

**See Important Safety Information for ALIMTA on pages 20-23.** For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Dosing and Administration,¹ Continued

Dosing and Administration for ALIMTA in Combination With Cisplatin for First-line Treatment of Advanced NS NSCLC or MPM

<table>
<thead>
<tr>
<th>Indication</th>
<th>ALIMTA</th>
<th>Cisplatin</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st-line therapy for advanced NS NSCLC</td>
<td>500 mg/m² IV over 10 minutes on day 1 of each 21-day cycle</td>
<td>Refer to the prescribing information for cisplatin.</td>
</tr>
<tr>
<td>MPM</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- In first-line therapy for advanced nonsquamous NSCLC, administer ALIMTA in combination with cisplatin for up to six cycles in the absence of disease progression or unacceptable toxicity.
- For MPM, administer ALIMTA in combination with cisplatin until disease progression or unacceptable toxicity.
- ALIMTA dosing recommendations are provided for patients with a creatinine clearance (calculated by Cockcroft-Gault equation) of 45 mL/min or greater. There is no recommended dose for patients whose creatinine clearance is less than 45 mL/min
- Initiate folic acid 400 mcg to 1000 mcg orally once daily, beginning 7 days before the first dose of ALIMTA and continuing until 21 days after the last dose of ALIMTA
- Patients must also receive one intramuscular injection of vitamin B₁₂ (1000 mcg) 1 week prior to the first dose of ALIMTA and every 3 cycles thereafter. Subsequent vitamin B₁₂ injections may be given the same day as treatment with ALIMTA. **Do not substitute oral vitamin B₁₂ for intramuscular vitamin B₁₂**
- Patients should receive dexamethasone 4 mg orally twice daily for 3 consecutive days, beginning the day before each ALIMTA administration.

Dosing modification notes
- In patients with creatinine clearances between 45 mL/min and 79 mL/min, avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of ALIMTA. Monitor patients more frequently for myelosuppression, renal, and gastrointestinal toxicity. If concomitant administration of ibuprofen cannot be avoided
- Obtain complete blood count on days 1, 8, and 15 of each cycle. Assess creatinine clearance prior to each cycle. Do not administer ALIMTA if the creatinine clearance is less than 45 mL/min
- Delay initiation of the next cycle of ALIMTA until recovery of nonhematologic toxicity to grade 0-2, ANC is 1500 cells/mm³ or higher, and platelet count is 100,000 cells/mm³ or higher
- Upon recovery, modify the dosage of ALIMTA in the next cycle as specified in the full Prescribing Information
- For dosing modifications for cisplatin, refer to the prescribing information for cisplatin

Select Important Safety Information

**Warnings and Precautions**

**Renal Failure:** ALIMTA can cause severe, and sometimes fatal, renal toxicity. Determine creatinine clearance before each dose and periodically monitor renal function during treatment with ALIMTA. Withhold ALIMTA in patients with a creatinine clearance of less than 45 mL/min.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Dosing and Administration,\(^1\) Continued

Dosing and Administration for ALIMTA as a Single Agent For Maintenance Treatment of Advanced NS NSCLC and Second-line Treatment of Recurrent Metastatic NS NSCLC After Prior Chemotherapy

**Table of Contents**

- Lilly PatientOne Co-pay Program
- ALIMTA Important Safety Information
- ALIMTA Product Distribution and Specifications
- ALIMTA Dosing and Administration
- ALIMTA Billing and Coding Information

---

**Indication**

<table>
<thead>
<tr>
<th>Maintenance for advanced NS NSCLC</th>
<th>ALIMTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd-line for recurrent metastatic NS NSCLC</td>
<td>500 mg/m(^2) IV over 10 minutes on day 1 of each 21-day cycle</td>
</tr>
</tbody>
</table>

- For maintenance therapy, ALIMTA is given until disease progression or unacceptable toxicity after four cycles of platinum-based first-line chemotherapy.
- For second-line therapy, ALIMTA is given until disease progression or unacceptable toxicity.
- ALIMTA dosing recommendations are provided for patients with a creatinine clearance (calculated by Cockcroft-Gault equation) of 45 mL/min or greater. There is no recommended dose for patients whose creatinine clearance is less than 45 mL/min.
- Initiate folic acid 400 mcg to 1000 mcg orally once daily, beginning 7 days before the first dose of ALIMTA and continuing until 21 days after the last dose of ALIMTA.
- Patients must also receive one intramuscular injection of vitamin B\(_{12}\) (1000 mcg) 1 week prior to the first dose of ALIMTA and every 3 cycles thereafter. Subsequent vitamin B\(_{12}\) injections may be given the same day as treatment with ALIMTA. Do not substitute oral vitamin B\(_{12}\) for intramuscular vitamin B\(_{12}\).
- Patients should receive dexamethasone 4 mg orally twice daily for 3 consecutive days, beginning the day before each ALIMTA administration.

**Dosing modification notes**

- In patients with creatinine clearances between 45 mL/min and 79 mL/min, avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of ALIMTA. Monitor patients more frequently for myelosuppression, renal, and gastrointestinal toxicity, if concomitant administration of ibuprofen cannot be avoided.
- Obtain complete blood count on days 1, 8, and 15 of each cycle. Assess creatinine clearance prior to each cycle. Do not administer ALIMTA if the creatinine clearance is less than 45 mL/min.
- Delay initiation of the next cycle of ALIMTA until recovery of nonhematologic toxicity to grade 0-2, ANC is 1500 cells/mm\(^3\) or higher, and platelet count is 100,000 cells/mm\(^3\) or higher.
- Upon recovery, modify the dosage of ALIMTA in the next cycle as specified in the full Prescribing Information.

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**Select Important Safety Information**

**Warnings and Precautions**

**Bullous and Exfoliative Skin Toxicity:** Serious and sometimes fatal, bullous, blistering, and exfoliative skin toxicity, including cases suggestive of Stevens-Johnson Syndrome/Toxic epidermal necrolysis, can occur with ALIMTA. Permanently discontinue ALIMTA for severe and life-threatening bullous, blistering, or exfoliating skin toxicity.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Dosing and Administration,\textsuperscript{1} Continued

Dosing Modifications: ALIMTA in Combination With Cisplatin, ALIMTA in Combination With Cisplatin or Carboplatin and Pembro, and ALIMTA as a Single Agent\textsuperscript{1}

Recommended dosage modifications for adverse reactions\textsuperscript{a}

<table>
<thead>
<tr>
<th>Toxicity in most recent treatment cycle</th>
<th>ALIMTA dose modification for next cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myelosuppressive toxicity</td>
<td></td>
</tr>
<tr>
<td>ANC less than 500/mm\textsuperscript{3} and platelets greater than or equal to 50,000/mm\textsuperscript{3}</td>
<td>75% of previous dose</td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Platelet count less than 50,000/mm\textsuperscript{3} without bleeding</td>
<td>50% of previous dose</td>
</tr>
<tr>
<td>Platelet count less than 50,000/mm\textsuperscript{3} with bleeding</td>
<td>Discontinue</td>
</tr>
<tr>
<td>Recurrent grade 3 or 4 myelosuppression after two dose reductions</td>
<td>Discontinue</td>
</tr>
<tr>
<td>Nonhematologic toxicity</td>
<td></td>
</tr>
<tr>
<td>Any grade 3 or 4 toxicities EXCEPT mucositis or neurologic toxicity</td>
<td>75% of previous dose</td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Diarrhea requiring hospitalization</td>
<td>50% of previous dose</td>
</tr>
<tr>
<td>Grade 3 or 4 mucositis</td>
<td>50% of previous dose</td>
</tr>
<tr>
<td>Renal toxicity</td>
<td>Withhold until creatinine clearance is 45 mL/min or greater</td>
</tr>
<tr>
<td>Grade 3 or 4 neurologic toxicity</td>
<td>Permanently discontinue</td>
</tr>
<tr>
<td>Recurrent grade 3 or 4 nonhematologic toxicity after two dose reductions</td>
<td>Permanently discontinue</td>
</tr>
<tr>
<td>Severe and life-threatening skin toxicity</td>
<td>Permanently discontinue</td>
</tr>
<tr>
<td>Interstitial pneumonitis</td>
<td>Permanently discontinue</td>
</tr>
</tbody>
</table>

Dosing modification notes
- Obtain complete blood count on days 1, 8, and 15 of each cycle. Assess creatinine clearance prior to each cycle. Do not administer ALIMTA if the creatinine clearance is less than 45 mL/min.
- Delay initiation of the next cycle of ALIMTA until recovery of nonhematologic toxicity to grade 0-2, ANC is 1500 cells/mm\textsuperscript{3} or higher, and platelet count is 100,000 cells/mm\textsuperscript{3} or higher.
- Upon recovery, modify the dosage of ALIMTA in the next cycle as specified in the table on this page.
- For dosing modifications for cisplatin, carboplatin, and pembro, refer to the respective prescribing information for each medication.

Select Important Safety Information

Warnings and Precautions

Serious Interstitial Pneumonitis: Pneumonitis, including fatal cases, can occur with ALIMTA treatment. Withhold ALIMTA for acute onset of new or progressive unexplained pulmonary symptoms such as dyspnea, cough, or fever pending diagnostic evaluation. If pneumonitis is confirmed, permanently discontinue ALIMTA.

\textsuperscript{a}National Cancer Institute Common Toxicity Criteria for Adverse Events (NCI CTCAE) version 2.0.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Dosing and Administration,\textsuperscript{1,2} Continued

Step-by-Step Preparation for Administration of the ALIMTA Intravenous Infusion\textsuperscript{1,2}

1. ALIMTA is a cytotoxic drug.\textsuperscript{1} Follow applicable special handling and disposal procedures\textsuperscript{2}

2. Calculate the dose of ALIMTA and determine the number of vials needed\textsuperscript{1}

3. Reconstitute ALIMTA to achieve a concentration of 25 mg/mL as follows\textsuperscript{1}:
   - Reconstitute each 100-mg vial with 4.2 mL of 0.9% Sodium Chloride Injection, USP (preservative-free)
   - Reconstitute each 500-mg vial with 20 mL of 0.9% Sodium Chloride Injection, USP (preservative-free)
   - Do not use calcium-containing solutions for reconstitution
   - Gently swirl each vial until the powder is completely dissolved. The resulting solution is clear and ranges in color from colorless to yellow or green-yellow
   - FURTHER DILUTION IS REQUIRED prior to administration
   - Store reconstituted, preservative-free product under refrigerated conditions [2-8°C (36-46°F)] for no longer than 24 hours from the time of reconstitution. Discard vial after 24 hours

4. Inspect the vial\textsuperscript{1}:
   - Inspect reconstituted product visually for particulate matter and discoloration prior to further dilution. If particulate matter is observed, discard vial

5. Dilute the infusion solution\textsuperscript{1}:
   - Withdraw the calculated dose of ALIMTA from the vial(s) and discard vial with any unused portion
   - Further dilute ALIMTA with 0.9% Sodium Chloride Injection (preservative-free) to achieve a total volume of 100 mL for intravenous infusion
   - Store diluted, reconstituted product under refrigerated conditions [2-8°C (36-46°F)] for no more than 24 hours from the time of reconstitution. Discard after 24 hours

Select Important Safety Information

Warnings and Precautions

Radiation Recall: Radiation recall can occur with ALIMTA in patients who have received radiation weeks to years previously. Monitor patients for inflammation or blistering in areas of previous radiation treatment. Permanently discontinue ALIMTA for signs of radiation recall.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Dosing and Administration,¹ Continued

Storage and Handling Requirements
- Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)¹
- ALIMTA is a cytotoxic drug.¹ Follow applicable special handling and disposal procedures²

How Supplied
ALIMTA is a white-to-light yellow or green-yellow lyophilized powder supplied as 100-mg or 500-mg single-dose vials for reconstitution for intravenous infusion.

For more information on ALIMTA, visit www.ALIMTA.com. Contact Lilly Medical for answers to additional medical questions by visiting www.LillyMedical.com, where you can submit a written question or communicate electronically with a medical professional. Or, call The Lilly Answers Center (TLAC) at 1-800-LillyRX (1-800-545-5979) to speak with a medical professional by phone.

Select Important Safety Information

Warnings and Precautions
Increased Risk of Toxicity With Ibuprofen in Patients With Renal Impairment: Exposure to ALIMTA is increased in patients with mild to moderate renal impairment who take concomitant ibuprofen, increasing the risks of adverse reactions of ALIMTA. In patients with creatinine clearances between 45 mL/min and 79 mL/min, avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of ALIMTA. If concomitant ibuprofen use cannot be avoided, monitor patients more frequently for ALIMTA adverse reactions, including myelosuppression, renal, and gastrointestinal toxicity.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Billing and Coding Information

All coding and documentation requirements for drugs should be confirmed with each payer.

Diagnosis Codes

<table>
<thead>
<tr>
<th>Nonsquamous NSCLC</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ICD-10 Code</strong></td>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>C34.00</td>
<td>Unspecified main bronchus</td>
</tr>
<tr>
<td>C34.01</td>
<td>Right main bronchus</td>
</tr>
<tr>
<td>C34.02</td>
<td>Left main bronchus</td>
</tr>
<tr>
<td>C34.10</td>
<td>Upper lobe, unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.11</td>
<td>Upper lobe, right bronchus or lung</td>
</tr>
<tr>
<td>C34.12</td>
<td>Upper lobe, left bronchus or lung</td>
</tr>
<tr>
<td>C34.2</td>
<td>Middle lobe, bronchus or lung</td>
</tr>
<tr>
<td>C34.30</td>
<td>Lower lobe, unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.31</td>
<td>Lower lobe, right bronchus or lung</td>
</tr>
<tr>
<td>C34.32</td>
<td>Lower lobe, left bronchus or lung</td>
</tr>
<tr>
<td>C34.80</td>
<td>Overlapping sites of unspecified bronchus and lung</td>
</tr>
<tr>
<td>C34.81</td>
<td>Overlapping sites of right bronchus and lung</td>
</tr>
<tr>
<td>C34.82</td>
<td>Overlapping sites of left bronchus and lung</td>
</tr>
<tr>
<td>C34.90</td>
<td>Unspecified part of unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.91</td>
<td>Unspecified part of right bronchus or lung</td>
</tr>
<tr>
<td>C34.92</td>
<td>Unspecified part of left bronchus or lung</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MPM</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ICD-10 Code</strong></td>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>C38.4</td>
<td>Malignant neoplasm of pleura</td>
</tr>
<tr>
<td>C45.0</td>
<td>Mesothelioma of pleura</td>
</tr>
</tbody>
</table>

HCPCS Codes

<table>
<thead>
<tr>
<th>ALIMTA Specific Code</th>
<th>Description</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>J9305</td>
<td>Injection, pemetrexed, 10 mg</td>
<td>Physician office and hospital outpatient</td>
</tr>
</tbody>
</table>


Select Important Safety Information

Warnings and Precautions

Embryo-Fetal Toxicity: Based on findings from animal studies and its mechanism of action, ALIMTA can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with ALIMTA and for 6 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with ALIMTA and for 3 months after the final dose.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Billing and Coding Information, Continued

All coding and documentation requirements for drugs should be confirmed with each payer.

Drug Administration CPT® Codes

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96409</td>
<td>Chemotherapy administration, intravenous, push technique, single or initial substance/drug</td>
</tr>
<tr>
<td>96411</td>
<td>Chemotherapy administration, intravenous, push technique, each additional substance/drug</td>
</tr>
<tr>
<td>96413</td>
<td>Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug</td>
</tr>
<tr>
<td>96415</td>
<td>Chemotherapy administration, intravenous infusion technique; each additional hour</td>
</tr>
<tr>
<td>96417</td>
<td>Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour</td>
</tr>
</tbody>
</table>

National Drug Code (NDC) for ALIMTA

<table>
<thead>
<tr>
<th>Vial Size</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 mg</td>
<td>00002-7623-01*</td>
</tr>
<tr>
<td>100 mg</td>
<td>00002-7640-01*</td>
</tr>
</tbody>
</table>

*FDA standard NDC has been “zero-filled” to ensure creation of an 11-digit code that meets HIPAA standards. The zero-fill location is indicated in bold.


CPT is a registered trademark of the American Medical Association.

Select Important Safety Information

**DRUG INTERACTIONS**

- Ibuprofen increases exposure (AUC) of pemetrexed. In patients with creatinine clearance between 45 mL/min and 79 mL/min:
  - Avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of ALIMTA.
  - Monitor patients more frequently for myelosuppression, renal, and gastrointestinal toxicity, if concomitant administration of ibuprofen cannot be avoided.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Sample Claim Form CMS-1450 (UB-04)
(Hospital Outpatient)

All coding and documentation requirements for drugs should be confirmed with each payer.

**FL 42 & 43: REVENUE CODES AND DESCRIPTION**
Enter the revenue codes that correspond to HCPCS or CPT codes outlined in FL 44. Payers may vary on revenue code requirements for each procedure/service performed.

**FL 44: PRODUCT AND PROCEDURE CODING**
Enter the HCPCS drug code and CPT code for the administration of ALIMTA.

**HCPCS:**
J9305: Injection, pemetrexed, 10 mg

**CPT:**
96409: Chemotherapy administration, intravenous, push technique, single or initial substance/drug
96411: Chemotherapy administration, intravenous, push technique, each additional substance/drug
96413: Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415: Chemotherapy administration, intravenous infusion technique; each additional hour
96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour

Please see additional CMS-1450 claim form information on page 12.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Sample Claim Form CMS-1450 (UB-04)
(Hospital Outpatient), Continued

All coding and documentation requirements for drugs should be confirmed with each payer.

- **FL 46: SERVICE UNITS**
  Specify the appropriate number of service units as designated by individual payers. Check to confirm the unit of use established by other payers, as there may be variation.

- **FL 66: DIAGNOSIS CODES**
  Enter the appropriate ICD diagnosis code(s) that correspond(s) to the type and location of the disease with which the patient has been diagnosed.

- **FL 80: REMARKS**
  To support the review and payment of the claim, include additional information as required by respective payers. This may include NDC, total dosage, and date ALIMTA was administered.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Sample Claim Form CMS-1500
(Physician Office)

All coding and documentation requirements for drugs should be confirmed with each payer.

BOX 19: ADDITIONAL CLAIM INFORMATION

Box 19 of the CMS-1500 claim form (or its electronic equivalent) is frequently utilized to obtain information regarding the use of drugs. The information will vary, but may include some or all of these items:

- Drug name
- NDC
- Total dose administered
- Route of administration
- Amount of drug wasted

BOX 21: DIAGNOSIS OR NATURE OF ILLNESS OR INJURY

Enter the appropriate diagnosis code on lines A-L to identify the patient’s diagnosis/condition and the applicable ICD indicator to identify which ICD code version is being reported. Use the highest level of specificity.

BOX 24A: DATE(S) OF SERVICE

When required by payers to provide the NDC, enter the code in the shaded areas of item number 24.

Please see additional CMS-1500 claim form information on page 14.

Sample Claim Form CMS-1500
(Physician Office)

All coding and documentation requirements for drugs should be confirmed with each payer.

BOX 19: ADDITIONAL CLAIM INFORMATION

Box 19 of the CMS-1500 claim form (or its electronic equivalent) is frequently utilized to obtain information regarding the use of drugs. The information will vary, but may include some or all of these items:

- Drug name
- NDC
- Total dose administered
- Route of administration
- Amount of drug wasted

BOX 21: DIAGNOSIS OR NATURE OF ILLNESS OR INJURY

Enter the appropriate diagnosis code on lines A-L to identify the patient’s diagnosis/condition and the applicable ICD indicator to identify which ICD code version is being reported. Use the highest level of specificity.

BOX 24A: DATE(S) OF SERVICE

When required by payers to provide the NDC, enter the code in the shaded areas of item number 24.

Please see additional CMS-1500 claim form information on page 14.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Sample Claim Form CMS-1500
(Physician Office), Continued

All coding and documentation requirements for drugs should be confirmed with each payer.

BOX 24D: PROCEDURES, SERVICES, OR SUPPLIES
Enter the HCPCS or CPT code and modifier(s) from the appropriate code set.

HCPCS:
J9305: Injection, pemetrexed, 10 mg

CPT:
96409: Chemotherapy administration, intravenous, push technique, single or initial substance/drug
96411: Chemotherapy administration, intravenous, push technique, each additional substance/drug
96413: Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415: Chemotherapy administration, intravenous infusion technique; each additional hour
96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour

BOX 24E: DIAGNOSIS POINTER
Enter the diagnosis code reference letter, as shown in Box 21, to relate the date of service and the procedures performed to the primary diagnosis. Enter only one reference letter per line item.

BOX 24G: DAYS OR UNITS
Specify the appropriate number of service units as designated by individual payers. Check to confirm the unit of use established by each payer, as there may be variation.

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
# ALIMTA Product Distribution

<table>
<thead>
<tr>
<th>Authorized Distributors</th>
<th>Contact Information</th>
</tr>
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<tbody>
<tr>
<td>AmerisourceBergen Corporation (includes Bellco)</td>
<td>800-829-3132</td>
</tr>
<tr>
<td>AmerisourceBergen Specialty Group (includes ASD Specialty Healthcare Inc., Besse Medical, Oncology Supply)</td>
<td>800-746-6273 (ASD Specialty Healthcare, Inc.) 800-543-2111 (Besse Medical) 800-633-7555 (Oncology Supply)</td>
</tr>
<tr>
<td>Anda Inc.</td>
<td>800-331-2632</td>
</tr>
<tr>
<td>Burlington Drug</td>
<td>800-551-9162</td>
</tr>
<tr>
<td>Capital Wholesale</td>
<td>800-282-2754</td>
</tr>
<tr>
<td>Cardinal Health (includes Kinray Inc.)</td>
<td>800-926-3161 (Cardinal Health) 888-527-6806 (Kinray Inc.)</td>
</tr>
<tr>
<td>CuraScript Specialty Distribution</td>
<td>877-599-7748</td>
</tr>
<tr>
<td>Dakota Drug Inc.</td>
<td>800-437-2018</td>
</tr>
<tr>
<td>H.D. Smith Wholesale Drug Company</td>
<td>866-232-1222</td>
</tr>
<tr>
<td>McKesson Corporation</td>
<td>800-482-3784</td>
</tr>
<tr>
<td>McKesson Specialty (includes U.S. Oncology)</td>
<td>800-482-6700</td>
</tr>
<tr>
<td>Miami-Luken Inc.</td>
<td>800-999-0302</td>
</tr>
<tr>
<td>Morris &amp; Dickson Company Ltd.</td>
<td>800-388-3833</td>
</tr>
<tr>
<td>Mutual Drug</td>
<td>800-800-8551</td>
</tr>
<tr>
<td>Prescription Supply Inc.</td>
<td>800-777-0761</td>
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<tr>
<td>Rochester Drug Company</td>
<td>800-922-9597</td>
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<tr>
<td>Smith Drug Company</td>
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<tr>
<td>Valley Wholesale Drug</td>
<td>800-247-6255</td>
</tr>
<tr>
<td>Value Wholesale Drug</td>
<td>800-252-3786</td>
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</table>

For more information on purchasing, dispensing, or returning Lilly products, visit [www.LillyTrade.com](http://www.LillyTrade.com). For inquiries about product supply, contact Lilly at **1-800-821-0538 Monday-Friday, 8 AM–5 PM ET.**

See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
## ALIMTA Product Specifications

### Packing Information

<table>
<thead>
<tr>
<th>Specifications</th>
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<td>00002-7640-01*</td>
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<td>300027640013</td>
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<td>VL7640001AM</td>
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<td>$690.05</td>
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<td>1 vial</td>
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<td><strong>Case Quantity</strong></td>
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<tr>
<td><strong>Case Dimensions</strong></td>
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<td>18.94 x 9.29 x 6.30 in</td>
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<tr>
<td><strong>Case Weight</strong></td>
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<tr>
<td><strong>Pallet Quantity</strong></td>
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<td>60 cases/pallet</td>
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<tr>
<td><strong>Pallet Dimensions</strong></td>
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<td>48 x 42 x 44 in</td>
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<tr>
<td><strong>Pallet Weight</strong></td>
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</tr>
</tbody>
</table>

UPC=Universal Product Code; WAC=wholesale acquisition cost.

*FDA standard NDC has been “zero-filled” to ensure creation of an 11-digit code that meets HIPAA standards. The zero-fill location is indicated in bold.

†WAC is the listed price to the distribution channel not including prompt pay, service, or administrative fees, stocking or distribution allowances, or any other discounts, rebates, or chargebacks provided by Lilly to any entity. WAC as of January 2019.

‡Uses standard corrugated boxes (RSCs).

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See Important Safety Information for ALIMTA on pages 20-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
The Lilly PatientOne Co-pay Program

With the Lilly PatientOne Co-pay Program, commercially insured, eligible patients treated with an FDA-approved indication for ALIMTA pay no more than $25 per dose with a maximum patient benefit of $25,000 during the 12-month enrollment period**‡

1. Review program eligibility with your patient.

2. For eligible patients, obtain an application by visiting LillyPatientOne.com and applying online or download an application to complete and fax. If downloading the application, please return all pages (including p. 2), via fax, to 1-877-366-0585. For questions or concerns, please call Lilly PatientOne at 1-866-4PatOne (1-866-472-8663).

3. After submitting the Lilly PatientOne Co-pay Program application, patients and providers will be informed of program enrollment status by Lilly PatientOne, indicating whether the patient meets eligibility requirements.

4. Once your patient is enrolled, please submit claims for financial assistance to Lilly PatientOne.

Reimbursement Timeline Overview

For enrolled patients, the Program may provide support for doses with a date of service that falls within 120 days prior to the date the application is received by the Program.

- Date of Infusion: For enrolled patients, a claim for reimbursement must be submitted within 180 days of infusion to receive Program benefits.

**See full patient eligibility criteria and terms and conditions on page 19.
†Eligible patients treated with ALIMTA must be commercially insured.
‡Patients who continue ALIMTA treatment and wish to participate in the Lilly PatientOne Co-pay Program must re-enroll every 12-month period.

THIS OFFER IS INVALID FOR PATIENTS WHOSE PRESCRIPTION CLAIMS ARE ELIGIBLE TO BE REIMBURSED, IN WHOLE OR IN PART, BY ANY GOVERNMENTAL PROGRAM.
Lilly PatientOne: Reimbursement Support

Find easy-to-use forms and reimbursement information to help support your patient’s treatment journey. Lilly PatientOne is committed to helping eligible patients access support programs for Lilly Oncology products they are prescribed. We aim to address both financial and coverage issues for qualified uninsured, underinsured, and insured patients. Lilly PatientOne strives to offer resources, ranging from benefits investigations to financial assistance and appeals information, that provide reliable and individualized treatment support for eligible patients.

Insurance Expertise

- Coding and billing information
- Payment methodologies and allowables
- Payer policy information

Reimbursement Assistance

- Eligibility determination
- Benefits investigation
- Prior authorization assistance
- Appeals information

For more information about Lilly PatientOne, call 1-866-4PatOne (1-866-472-8663), Monday–Friday, 9 AM–7 PM ET, or visit LillyPatientOne.com.
Lilly PatientOne Co-pay Program Terms and Conditions (Effective September 1, 2018)

**Eligibility:** 1. You have been prescribed one of the following Lilly Oncology medicines covered by the Lilly PatientOne Co-pay Program ("Program"): Alimta® [pemetrexed for injection], Cyramza® [ramucirumab], Erbitux® [cetuximab], Portrazza® [necitumumab], or Lartruvo® [olaratumab] [hereinafter collectively referred to as "prescribed Lilly Oncology medicine"]. 2. You have commercial insurance that covers your prescribed Lilly Oncology medicine, but your insurance does not cover the full cost; that is, you have a co-pay or coinsurance obligation. 3. You are not participating in any state or federal healthcare program, including, without limitation, Medicaid, Medicare, Medigap, CHAMPUS, DOD, VA, TRICARE, or any state patient, or pharmaceutical assistance program; patients who move from commercial insurance to a state or federal healthcare program will no longer be eligible. 4. You are 18 years of age or older and are receiving your prescribed Lilly Oncology medicine for an FDA-approved use. Please ask your doctor for information about FDA-approved uses. Also see your doctor for the full US Prescribing Information for your prescribed Lilly Oncology medicine. 5. You are a resident of the United States or Puerto Rico.

**Program Benefits:** 6. The patient must first pay a portion of his or her co-pay or coinsurance ($25 for each dose of the patient’s prescribed Lilly Oncology medicine). The Program will cover the remainder of the patient’s co-pay or coinsurance for the prescribed Lilly Oncology medicine, up to a monthly cap of wholesale acquisition cost plus usual and customary fees and a maximum of $25,000 during a 12-month enrollment period. 7. In order to receive Program benefits, the patient or healthcare provider must submit an Explanation of Payment (EOP) form. The submitted form must include the name of the insurer and plan, and show that the prescribed Lilly Oncology medicine was the medication that was administered. 8. For enrolled patients, a claim for reimbursement must be submitted within 180 days of infusion to receive Program benefits. 9. Program benefits are limited to the co-pay or coinsurance costs for doses of the prescribed Lilly Oncology medicine only. The Program will not cover, and shall not be applied toward, the cost of any dosing procedure, any other healthcare provider service or supply charges or other treatment costs, or any costs associated with a hospital stay. 10. For enrolled patients, the Program may provide support for doses with a date of service that falls within 120 days prior to the date the application is received by the Program.

**Program Timing:** 11. Patients must enroll on or before December 31, 2019, to be eligible to receive benefits. 12. If you live in Massachusetts, the Program co-pay card for a particular Lilly Oncology medicine expires on the earlier of: (i) the expiration date of the Program co-pay card (December 31, 2019); (ii) the date an AB rated generic equivalent becomes available; or (iii) June 30, 2019, absent a change in Massachusetts state law. If you live in California, the card for a particular Lilly Oncology medicine expires on the earlier of: (i) the expiration date of Program co-pay card (December 31, 2019); or (ii) the date an FDA-approved therapeutically equivalent becomes available or over-the-counter product with the same active ingredients becomes available.

**Additional Program Terms and Conditions:** 13. Patients, pharmacists, and healthcare providers must not seek reimbursement from health insurance or any third party for any part of the benefit received by the patient through this Program. Patients must not seek reimbursement from any health savings, flexible spending, or other healthcare reimbursement accounts for the amount of assistance received from the Program. 14. Acceptance of this offer confirms that this offer is consistent with your insurance and that you will report the value of the co-pay assistance you receive as may be required by your insurance provider. 15. This offer is not valid with any other financial support program, Patient Assistance Program (PAP), discount, or incentive involving the prescribed Lilly Oncology medicine. 16. Only valid in the United States and Puerto Rico; this offer is void where restricted or prohibited by law. 17. The Program benefits are nontransferable. 18. This offer is not conditioned on any past, present, or future purchase, including additional doses. 19. The Program is not insurance. 20. Lilly USA, LLC reserves the right to terminate, rescind, revoke, or amend this offer at any time without notice.
Important Safety Information for ALIMTA® (pemetrexed for injection)

**Contraindication**

• ALIMTA is contraindicated in patients who have a history of severe hypersensitivity reaction to pemetrexed.

**WARNINGS AND PRECAUTIONS**

**Myelosuppression and Increased Risk of Myelosuppression Without Vitamin Supplementation**

• ALIMTA can cause severe myelosuppression resulting in a requirement for transfusions and which may lead to neutropenic infection. The risk of myelosuppression is increased in patients who do not receive vitamin supplementation.

• Prior to treatment with ALIMTA, patients must be instructed to initiate supplementation with oral folic acid. Intramuscular injections of vitamin B₁₂ are also required prior to ALIMTA treatment. Folic acid and vitamin B₁₂ supplementation should be continued during treatment and for 21 days after the last dose of ALIMTA as they may reduce the severity of treatment-related hematologic and gastrointestinal toxicities. Obtain a complete blood count at the beginning of each cycle. Do not administer ALIMTA until the ANC is at least 1500 cells/mm³ and platelet count is at least 100,000 cells/mm³. Permanently reduce ALIMTA in patients with an ANC of less than 500 cells/mm³ or platelet count of less than 50,000 cells/mm³ in previous cycles.

• In Studies JMDB and JMCH, among patients who received vitamin supplementation, incidence of Grade 3-4 neutropenia was 15% and 23%, the incidence of Grade 3-4 anemia was 6% and 4%, and incidence of Grade 3-4 thrombocytopenia was 4% and 5%, respectively. In Study JMCH, 18% of patients in the ALIMTA arm required red blood cell transfusions compared to 7% of patients in the cisplatin arm. In Studies JMEN, PARAMOUNT, and JMEI, where all patients received vitamin supplementation, incidence of Grade 3-4 neutropenia ranged from 3% to 5%, and incidence of Grade 3-4 anemia ranged from 3% to 5%.

**Renal Failure**

• ALIMTA can cause severe, and sometimes fatal, renal toxicity. Determine creatinine clearance before each dose and periodically monitor renal function during treatment with ALIMTA.

• The incidences of renal failure in clinical studies in which patients received ALIMTA with cisplatin were: 2.1% in Study JMDB and 2.2% in Study JMCH. The incidence of renal failure in clinical studies in which patients received ALIMTA as a single agent ranged from 0.4% to 0.6% (Studies JMEN, PARAMOUNT, and JMEI).

• Withhold ALIMTA in patients with a creatinine clearance of less than 45 mL/min.

**Bullous and Exfoliative Skin Toxicity**

• Serious and sometimes fatal, bullous, blistering and exfoliative skin toxicity, including cases suggestive of Stevens-Johnson Syndrome/toxic epidermal necrolysis can occur with ALIMTA. Permanently discontinue ALIMTA for severe and life-threatening bullous, blistering or exfoliating skin toxicity.

**Interstitial Pneumonitis**

• Serious interstitial pneumonitis, including fatal cases, can occur with ALIMTA treatment. Withhold ALIMTA for acute onset of new or progressive unexplained pulmonary symptoms such as dyspnea, cough, or fever pending diagnostic evaluation. If pneumonitis is confirmed, permanently discontinue ALIMTA.

**Radiation Recall**

• Radiation recall can occur with ALIMTA in patients who have received radiation weeks to years previously. Monitor patients for inflammation or blistering in areas of previous radiation treatment. Permanently discontinue ALIMTA for signs of radiation recall.

See Important Safety Information for ALIMTA continued on pages 21-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Important Safety Information for ALIMTA® (pemetrexed for injection), Continued

WARNINGS AND PRECAUTIONS, Continued

Increased Risk of Toxicity With Ibuprofen in Patients With Renal Impairment

- Exposure to ALIMTA is increased in patients with mild to moderate renal impairment who take concomitant ibuprofen, increasing the risks of adverse reactions of ALIMTA. In patients with creatinine clearances between 45 mL/min and 79 mL/min, avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of ALIMTA. If concomitant ibuprofen use cannot be avoided, monitor patients more frequently for ALIMTA adverse reactions, including myelosuppression, renal, and gastrointestinal toxicity.

Embryo-Fetal Toxicity

- Based on findings from animal studies and its mechanism of action, ALIMTA can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, intravenous administration of pemetrexed to pregnant mice during the period of organogenesis was teratogenic, resulting in developmental delays and increased malformations at doses lower than the recommended human dose of 500 mg/m². Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with ALIMTA and for 6 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with ALIMTA and for 3 months after the final dose.

DRUG INTERACTIONS

- Ibuprofen increases exposure (AUC) of pemetrexed. In patients with creatinine clearance between 45 mL/min and 79 mL/min:
  - Avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of ALIMTA.
  - Monitor patients more frequently for myelosuppression, renal, and gastrointestinal toxicity, if concomitant administration of ibuprofen cannot be avoided.

ADVERSE REACTIONS

- Severe adverse reactions (Grade 3-4) occurring in ≥20% of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC) receiving ALIMTA in combination with pembrolizumab and platinum chemotherapy (carboplatin or cisplatin) versus ALIMTA with platinum chemotherapy + placebo for initial treatment (KEYNOTE-189), respectively, were fatigue (12% vs 6%); diarrhea (5% vs 3%); dyspnea (3.7% vs 5%); vomiting (3.7% vs 3%); nausea (3.5% vs 3.5%); rash (2% vs 2.5%); decreased appetite (1.5% vs 0.5%); constipation (1% vs 0.5%); and pyrexia (0.2% vs 0%).

- Common adverse reactions (all grades) occurring in ≥20% of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC) receiving ALIMTA in combination with pembrolizumab and platinum chemotherapy (carboplatin or cisplatin) versus ALIMTA with platinum chemotherapy + placebo for initial treatment (KEYNOTE-189), respectively, were nausea (56% vs 52%); fatigue (56% vs 58%); constipation (35% vs 32%); diarrhea (31% vs 21%); decreased appetite (28% vs 30%); rash (25% vs 17%); vomiting (24% vs 23%); cough (21% vs 28%); dyspepsia (21% vs 26%); and pyrexia (20% vs 15%).

- Severe adverse reactions (Grade 3-4) occurring in fully vitamin supplemented patients with locally advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) receiving ALIMTA in combination with cisplatin versus gemcitabine in combination with cisplatin for initial treatment (JMDB), respectively, were neutropenia (15% vs 27%); fatigue (7% vs 5%); nausea (7% vs 4%); vomiting (6% vs 6%); anemia (6% vs 10%); thrombocytopenia (4% vs 13%); anorexia (2% vs 1%); creatinine elevation (1% vs 1%); diarrhea (1% vs 2%); stomatitis/pharyngitis (1% vs 0%); and constipation (1% vs 0%).

- Common adverse reactions (all grades) occurring in ≥5% fully vitamin supplemented patients with locally advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) receiving ALIMTA in combination with cisplatin versus gemcitabine in combination with cisplatin for initial treatment (JMDB), respectively, were nausea (56% vs 53%); fatigue (43% vs 45%); vomiting (40% vs 36%); anemia (33% vs 46%); neutropenia (29% vs 38%); anorexia (27% vs 24%); constipation (21% vs 20%); stomatitis/pharyngitis (14% vs 12%); alopecia (12% vs 21%); diarrhea (12% vs 13%); thrombocytopenia (10% vs 27%); creatinine elevation (10% vs 7%); sensory neuropathy (9% vs 12%); taste disturbance (8% vs 9%); rash/desquamation (7% vs 8%); and dyspepsia/heartburn (5% vs 6%).

See Important Safety Information for ALIMTA continued on pages 22-23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
ADVERSE REACTIONS, Continued

Important Safety Information for ALIMTA® (pemetrexed for injection), Continued

• Severe adverse reactions (Grade 3-4) occurring in patients with non-progressive locally advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) receiving ALIMTA as a single agent versus placebo as maintenance treatment (JMEN), respectively, following non-ALIMTA containing platinum-based induction therapy were anemia (3% vs 1%); neutropenia (3% vs 0%); fatigue (5% vs 1%); nausea (1% vs 1%); anorexia (2% vs 0%); infection (2% vs 0%); mucositis/stomatitis (1% vs 0%); diarrhea (1% vs 0%); and sensory neuropathy (1% vs 0%).

• Common adverse reactions (all grades) occurring in ≥5% patients with non-progressive locally advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) receiving ALIMTA as a single agent versus placebo as maintenance treatment (JMEN), respectively, following non-ALIMTA containing platinum-based induction therapy were fatigue (25% vs 11%); nausea (19% vs 6%); anorexia (19% vs 5%); anemia (15% vs 6%); increased rash/desquamation (10% vs 3%); ALT (10% vs 4%); sensory neuropathy (9% vs 4%); vomiting (9% vs 1%); increased AST (8% vs 4%); mucositis/stomatitis (7% vs 2%); neutropenia (6% vs 0%); diarrhea (5% vs 3%); and infection (5% vs 2%).

• Severe adverse reactions (Grade 3-4) occurring in patients with non-progressive locally advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) receiving ALIMTA as a single agent versus placebo as maintenance treatment (PARAMOUNT), respectively, following ALIMTA plus cisplatin induction therapy were anemia (4.8% vs 0.6%); neutropenia (3.9% vs 0%); nausea (0.3% vs 0%); and mucositis/stomatitis (0.3% vs 0%).

• Common adverse reactions (all grades) occurring in ≥5% patients with non-progressive locally advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) receiving ALIMTA as a single agent versus placebo as maintenance treatment (PARAMOUNT), respectively, following ALIMTA plus cisplatin induction therapy were fatigue (18% vs 11%); anemia (15% vs 4.8%); nausea (12% vs 2.4%); neutropenia (9% vs 0.6%); vomiting (6% vs 1.8%); mucositis/stomatitis (5% vs 2.4%); and edema (5% vs 3.6%).

• Severe adverse reactions (Grade 3-4) occurring in fully supplemented patients with recurrent metastatic nonsquamous non-small cell lung cancer (NSCLC) receiving ALIMTA as a single agent versus docetaxel as 2nd-line treatment after prior chemotherapy (JMEI), respectively, were neutropenia (5% vs 40%); fatigue (5% vs 5%); anemia (4% vs 4%); nausea (3% vs 2%); anorexia (2% vs 3%); vomiting (2% vs 1%); thrombocytopenia (2% vs 0%); increased ALT (2% vs 0%); increased AST (1% vs 0%); and stomatitis/pharyngitis (1% vs 1%).

• Common adverse reactions (all grades) occurring in ≥5% of fully supplemented patients with recurrent metastatic nonsquamous non-small cell lung cancer (NSCLC) receiving ALIMTA as a single agent versus docetaxel as 2nd-line treatment after prior chemotherapy (JMEI), respectively, were fatigue (34% vs 36%); nausea (31% vs 17%); anorexia (22% vs 24%); anemia (19% vs 22%); vomiting (16% vs 12%); stomatitis/pharyngitis (15% vs 17%); rash/desquamation (14% vs 6%); diarrhea (13% vs 24%); neutropenia (11% vs 45%); fever (8% vs 8%); thrombocytopenia (8% vs 1%); increased ALT (8% vs 1%); pruritus (7% vs 2%); increased AST (7% vs 1%); constipation (6% vs 4%); and alopecia (6% vs 38%).

• Severe adverse reactions (Grade 3-4) occurring in the fully supplemented subgroup of patients with malignant pleural mesothelioma (MPM) receiving ALIMTA in combination with cisplatin versus cisplatin alone (JMCH), respectively, were neutropenia (23% vs 3%); nausea (12% vs 6%); vomiting (11% vs 4%); fatigue (10% vs 9%); thrombocytopenia (5% vs 0%); dehydration (4% vs 1%); anemia (4% vs 0%); diarrhea (4% vs 0%); stomatitis/pharyngitis (3% vs 0%); creatinine elevation (1% vs 1%); anorexia (1% vs 1%); constipation (1% vs 1%); dyspepsia (1% vs 0%); sensory neuropathy (0% vs 1%); rash (1% vs 0%); and creatinine clearance decrease (1% vs 2%).

• Common adverse reactions (all grades) occurring in ≥5% of the fully supplemented subgroup of patients with malignant pleural mesothelioma (MPM) receiving ALIMTA in combination with cisplatin versus cisplatin alone (JMCH), respectively, were nausea (82% vs 77%); vomiting (57% vs 50%); neutropenia (56% vs 13%); fatigue (48% vs 42%); anemia (26% vs 10%); thrombocytopenia (23% vs 9%); stomatitis/pharyngitis (23% vs 6%); anorexia (20% vs 14%); diarrhea (17% vs 8%); creatinine clearance decreased (16% vs 18%); rash (16% vs 5%); constipation (12% vs 7%); creatinine elevation (11% vs 10%); alopecia (11% vs 6%); sensory neuropathy (10% vs 10%); conjunctivitis (5% vs 1%); dyspepsia (5% vs 1%); dehydration (7% vs 1%); and taste disturbance (8% vs 6%).

See Important Safety Information for ALIMTA continued on page 23. For safety and dosing guidelines, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information for ALIMTA.
Important Safety Information for ALIMTA® (pemetrexed for injection), Continued

USE IN SPECIFIC PATIENT POPULATIONS

• **Lactation:** There is no information regarding the presence of pemetrexed or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed infants from ALIMTA, advise women not to breastfeed during treatment with ALIMTA and for one week after last dose.

• **Males of Reproductive Potential:** ALIMTA may impair fertility in males of reproductive potential. It is not known whether these effects on fertility are reversible.

• **Pediatric Use:** The safety and effectiveness of ALIMTA in pediatric patients have not been established. Adverse reactions observed in pediatric patients studied were similar to those observed in adults.

• **Patients with Renal Impairment:** ALIMTA is primarily excreted by the kidneys. Decreased renal function results in reduced clearance and greater exposure (AUC) to ALIMTA compared with patients with normal renal function. No dose is recommended for patients with creatinine clearance less than 45 mL/min.

• **Geriatric:** The incidences of Grade 3-4 anemia, fatigue, thrombocytopenia, hypertension, and neutropenia were higher in patients 65 years of age and older as compared to younger patients: in at least one of five randomized clinical trials.

For safety and dosing guidelines for ALIMTA, see complete Warnings and Precautions, Adverse Reactions, and Dosage and Administration sections in the full Prescribing Information and Patient Prescribing Information.

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Reference: